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L1: Entry 1 of 1 File: USPT Jul 9, 1985

US-PAT-NO: 4528180
DOCUMENT-IDENTIFIER: US 4528180 A

TITLE: Dental preparation, article and method for storage and delivery thereof

DATE-ISSUED: July 9, 1985

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Schaeffer; Hans A.	Linden	NJ	07036	

APPL-NO: 06/ 471188 [PALM]
DATE FILED: March 1, 1983

INT-CL: [03] B65D 35/22, A61K 7/16, A61K 7/18, A61K 7/20

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US-CL-CURRENT: 424/52; 222/192, 222/92, 222/94, 424/53, 424/602, 424/616, 424/695, 424/698

FIELD-OF-SEARCH: 424/53, 424/130, 424/44, 222/92, 222/94, 222/192

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
☐	636986	November 1899	Heinen	424/130
☐	959605	May 1910	Queisser	424/130
☐	1535529	April 1925	Hopkins	424/53
☐	1566218	December 1925	Leland	424/49
☐	2035267	March 1936	Fleischman	424/53
☐	2054742	September 1936	Elbel	424/53
☐	2789731	April 1957	Marraffino	222/129
☐	3175731	March 1965	Ellman	424/52
☐	3499844	March 1970	Kibbel et al.	252/316
☐	3577521	May 1971	Scheller et al.	424/55
☐	3639574	February 1972	Schmolka	424/130
☐	3874558	April 1975	Rockefeller	222/92
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☐	3907991	September 1975	Accetta	424/130
☐	3937321	February 1976	Delaney et al.	206/84
☐	4060179	November 1977	McGhie	222/92
☐	4098435	July 1978	Weyn	222/94
☐	4130501	December 1978	Lutz et al.	252/186
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1492660	November 1977	GB	
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Goupil, Chem. Abstracts, 87#11477h, (1977) of Ger. Offen. No. 2,643,411, Apr. 7, 1977, (14 pages), (Compartmental Peroxide and Acid Toothpaste).

ART-UNIT: 123

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

The invention is directed to a combination of a collapsible tube article having flexible side walls and a composition consisting of a gel component and a paste component and contained in said article, said combination being suitable for use in combatting gum disease, said article comprising:

(a) a first compartment containing said gel, said gel comprising (i) 1-10% by volume of hydrogen peroxide, (ii) 0.05-1.2% by volume of a water dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) 0.1-1.5% by volume of a non-ionic cellulose gum stabilizer (iv) purified water and (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in an amount sufficient to raise the pH of said gel to within about 3-6 said first compartment having an orifice for dispensing controlled amounts of said gel upon squeezing of said flexible sidewalls;

(b) a second compartment containing said paste, said paste comprising (i) 10-50% by weight of sodium bicarbonate; (ii) 1-6% by weight of a salt selected from the group consisting of NaCl and MgSO.sub.4 ; (iii) 1-3% by weight of a thickener-stabilizer selected from the group consisting of cellulose gum magnesium aluminum silicate, and mixtures thereof; (iv) 5-30% by weight of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol and polypropylene glycol, (v) purified water and (vi) 1-40% by weight of a cleaning-polishing agent selected from the group consisting of CaSO.sub.4, Ca.sub.3 (PO.sub.4).sub.2 and hydrated aluminum oxide, and (viii) 0.1-2.5% by weight of sodium lauryl sulfate.

6 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 1

BRIEF SUMMARY:

1 This invention relates to a dental preparation useful in the treatment of gum disease, to a method of storing and delivering such preparation to a use point and to an article for the storage and delivery of such preparation.

2 It has long been recognized that the combination of hydrogen peroxide solution with sodium bicarbonate and table salt has an excellent curative and preventive effect on gum disease caused by bacterial infection. Dr. Paul H. Keyes has advocated use of this combination to the dental profession and to the public at large based on his work of more than 25 years on the subject, which has shown that upon daily and diligent topical application of these materials, gum disease may be effectively controlled. On the basis of his recommendations, many dentists urge their patients to use the Keyes procedure (substantially as described e.g. in S. Elder: "An Alternative To Gum Surgery" Modern Maturity, August-September 1980 pp. 31-32).

3 Dr. Keyes advocates that a quantity of solid sodium bicarbonate be placed in one hand, and that the toothbrush, held in the other hand, be dipped into a hydrogen peroxide--table salt solution and then transferred to the bicarbonate and applied to the teeth and gums. Upon contact with the gums, the hydrogen peroxide is exposed to the enzyme catalase, which is always present in the buccal cavity, and is attacked thereby resulting in the release of active oxygen. The combination of the active oxygen and the sodium bicarbonate together with table salt destroys the bacteria responsible for gum desease. Unfortunately, hydrogen peroxide and sodium bicarbonate may not be premixed, as they immediately react and are thereby rendered ineffective against gum desease. In addition, hydrogen peroxide is unstable and therefore difficult to store for prolonged periods of time. Finally, mere dipping of the toothbrush in a hydrogen peroxide solution does not insure delivery of a sufficient amount of hydrogen peroxide to the teeth and gums. These factors are responsible for the fact that use of the Keyes procedure is extremely awkward, inconvenient and messy. Another disadvantage stems from the fact that, the mixture of hydrogen peroxide and sodium bicarbonate has a very unpleasant taste. For these reasons, patients have shown extreme reluctance to follow this procedure, especially on a daily basis, as would be required for effective gum desease control. As a result, the benefits which the Keyes procedure affords have largely been left unrealized.

4 Accordingly, it is an object of this invention to eliminate the above

disadvantages associated with use of the Keyes procedure by providing a dental preparation incorporating the active constituents of the Keyes procedure that has pleasant taste and is neat and convenient to use, and a method for using such preparation that permits contact between hydrogen peroxide and sodium bicarbonate only shortly before use and, therefore, assures maximum effectiveness against gum disease.

5 It is another object of the present invention to provide a dental preparation incorporating the active constituents of the Keyes method and a method for using such preparation that permits a sufficient, consistent and reproducible amount of hydrogen peroxide to be delivered to the use point.

6 It is yet another object of this invention to provide an article for the storage and delivery of this improved dental preparation which makes its use neat and convenient and which prevents contact between hydrogen peroxide and sodium bicarbonate prior to application.

DETAILED DESCRIPTION:

1 In accordance with the present invention, hydrogen or urea peroxide is dissolved in an aqueous nontoxic gel for use in combination with a separately stored but substantially simultaneously dispensed paste containing sodium bicarbonate, table salt, and, preferably, additional cleansing and polishing agents as well as an effective concentration of flavoring substances. Each of the gel and paste are loaded either into separate collapsible containers which are connected by means of a common orifice (as in FIG. 1), or which have substantially adjacent orifices (as in FIG. 2), or in separate compartments of a single container (as in FIG. 3).

2 Upon substantially simultaneous squeezing of the containers, in much the same way as common toothpaste tubes, controlled quantities of the gel and paste can be simultaneously released onto the toothbrush and immediately applied to the teeth and gums. Control of the H.sub.2 O.sub.2, NaCl and NaHCO.sub.3 quantities delivered may be thus effected by specification of the opening of the orifice and the active ingredient concentration in each tube. As described above, when the brush is applied to teeth and gums, immediate mixing of the products takes place followed by the rapid evolution of active oxygen and carbon dioxide. At the same time, the effervescence accompanying release of active oxygen activates the flavor contained in the bicarbonate paste and produces a lasting highly refreshing taste in the mouth which is unlike any other flavor provided by existing toothpastes or gels. Another advantage afforded by the present invention, as compared with the Keyes procedure, is that a greater and more consistent amount of hydrogen peroxide is delivered to the use point.

3 Gelling agents suitable for use in preparation of the H.sub.2 O.sub.2 gel in accordance with this invention should be nontoxic and neutral to the hydrogen peroxide to assure its stability. In addition, they should be preferably sensitive to external electrolytes, such as those contained in the sodium bicarbonate paste, in order to make hydrogen peroxide immediately available to the oral tissues. A gelling agent suitable for use with the present invention is a copolymer of acrylic acid cross-linked with polyallyl sucrose, as described in U.S. Pat. No. 2,798,053 issued on July 2, 1957 and assigned to B. F. Goodrich Inc. Other gelling agents resulting in stable hydrogen peroxide gels suitable for use in the present invention include those described in British Pat. No. 827,331, i.e., organic polymeric acid colloids including polyuronic acids, carboxypolymethylene compounds and polyester resins containing three carboxyl groups, such as partially hydrolized polyacrylates or polymethacrylates and copolymers thereof; and those described in U.S. Pat. No. 3,639,574 issued on Feb. 1, 1972 to Schmolka, i.e., polyoxyethylene polyoxypropylene block copolymers, which, according to Schmolka, may be used in the preparation of stable, firm hydrogen peroxide gels. Preferred are water dispersible copolymers of acrylic acid cross-linked with about 0.75 to about

1.5% of polyallyl sucrose and neutralized with triethanolamine, NaOH or another alkalizing agent, as taught in U.S. Pat. No. 3,499,844.sup.1 issued on Mar. 10, 1970 to Kibbel et al. For purposes of the present invention, Kibbel's acrylic copolymer may be preferably combined with an anionic or non-ionic surfactant, such as disclosed in U.S. Pat. No. 4,130,501.sup.1 issued on Dec. 19, 1978 to Lutz et al. Such surfactants are not essential for the formation of a stable hydrogen peroxide gel in accordance with this invention, but may be added to facilitate distribution and rapid penetration of the active oxygen throughout the area to be treated. The most preferred gelling agent for the purposes of the present invention is that described by Kibbel, supra, modified by the addition of a suitable amount of non-ionic cellulose gum such as hydroxyethylor hydroxypropyl-cellulose or hydroxypropyl methylcellulose in order to improve the physical stability of the gel, especially when subjecting it to stress such as that resulting from squeezing of the collapsible tubes. In addition, a small quantity of a surfactant may be added in order to enhance the dispersibility of the gel when mixed with a sodium bicarbonate paste.

1 .sup.1 The disclosures of these patents are incorporated herein by reference.

4 The hydrogen peroxide gel may then contain the following ingredients in the following amounts --H.sub.2 O.sub.2 : about 1.0-10.0% and preferably about 3.0-6.5%; Acrylic acid copolymer: about 0.05-1.20% and, preferably, about 0.3-0.8%; nonionic cellulose gum: about 0.1-1.5% and, preferably, about 0.3-0.8%; neutralizing agent (triethanolamine, diisopropanolamine, NaOH, KOH): an amount sufficient to raise the gel pH to about 3.0-6.0. The balance is purified (distilled or deionized) water.

5 The sodium bicarbonate paste contains sodium bicarbonate, sodium chloride, purified (distilled or deionized) water and a thickener/stabilizer such as cellulose gum and magnesium-aluminum silicate, as essential ingredients. In order to disperse the "chalky" taste imparted mostly by the bicarbonate, a bodying agent is added, such a sorbitol, glycerin or a glycol. In addition, if the paste, in combination with the gel, is to displace toothpaste completely, cleansing agents, such as calcium sulfate, calcium phosphate and hydrated aluminum oxide, as well as a foaming agent such as sodium lauryl sulfate (which also enhances the peroxide-bicarbonate-salt action) may be added. Flavoring agents, such as sodium saccharin, or other artificial sweeteners, peppermint or spearmint or other flavors are preferably added to further curb the unpleasant taste. Finally, methyl and/or propyl paraben are preferably added as preservatives. Use of a coloring agent is optional.

6 The constituents and quantities for the bicarbonate paste are as follows: sodium bicarbonate: about 10-50% and preferably 20-40%; polyol: about 5-30% and preferably, 15-25%; cellulose gum: about 1-3% and preferably 1.2-1.8%; sodium chloride: about 1-6% and preferably about 2-4%; polishing agent/cleanser: about 1-40%, preferably about 1.5-30%; foaming agent: about 0.1-2.5% and preferably about 0.2-0.5%; flavoring agent(s): to taste, less than about 1%; preservatives: about 0.1-0.5%. The balance is purified water. The paste and the gel are preferably used in substantially equal proportions, by volume.

7 The gel and paste combination may be simultaneously dispensed from separate collapsible tubes preferably made of plastic, or a plastic/metal laminate (to avoid reaction with H.sub.2 O.sub.2), such as tubes 1 and 2 shown in FIG. 1. The tubes are fitted with a Y-shaped conduit 3 which provides them with a common orifice 6. Conduit 3 may also be made of plastic (preferably by injection molding) and is preferably detachably but snugly attached to mouths 4,5 of tubes 1,2 so that it may be removed for cleaning. For additional convenience and in order to ensure dispensation of substantially equal amounts of the gel and paste, the tubes themselves may be held together, e.g., by banding or cementing, along corresponding dorsal sides, shown in FIG. 1, or, preferably, along corresponding ventral sides (see, e.g., FIG. 3A).

8 Alternatively, the two tubes may be constructed to have a common (preferably flat) sidewall portion 26 as shown in FIG. 2. In the latter case, the Y-shaped

conduit may be unnecessary, if the mouths 24,25 of tubes 21,22 are sufficiently close so that sufficient quantities of the gel and paste may be simultaneously dispensed directly on the toothbrush. Conventional toothpaste or medicament tubes may be thus used after one of their side walls and the corresponding portion of their head structure are permanently deformed (e.g. by application of pressure) to a substantially flat surface.

9 A third alternative packaging method involves loading each of the gel and paste into separate compartments of the same collapsible tube, joined by a common orifice, as shown in FIG. 3. Composite tube 31 has compartments 32, 33 separated by divider 34 which is firmly attached along substantially diametrically opposed portions 35,36 of the sidewall 37, and corresponding portions 38,39 of head structure 40. Divider 34 may be glued or welded to sidewall 37 and head structure 40 of tube 31 during manufacture of the latter. Divider 34 is preferably provided with protruding portion 41, which extends into the mouth 42 of tube 31 until its edge is substantially flush with rim 43 of mouth 42. Thus, divider 34 forms with sidewall 37 two separate compartments 32,33 of substantially the same volume for storage of the gel and paste, respectively.

10 Tubes, such as those suitable for use in accordance with the present invention are usually extruded around a cylindrical mandrel, cut into tube segments of suitable length, fitted with head structures and then filled from the bottom and pressed and/or welded closed, substantially as described in, e.g., U.S. Pat. No. 4,060,179 issued on Nov. 29, 1977 to McGhie, the disclosure of which is incorporated herein by reference.

11 The invention is further illustrated by the following specific examples which are designed merely to illustrate the present invention and not to limit its scope.

12 In these examples, a hydrogen peroxide gel containing 3-6.5% hydrogen peroxide by weight, useful for simultaneous administration with a sodium bicarbonate paste is prepared as follows:

13 EXAMPLE 1

14 Ingredients

15 Hydrogen peroxide, 35% aqueous solution (5% H.sub.2 O.sub.2 in final gel): 14.3 parts

16 Purified water: 84.45

17 Copolymer of acrylic acid crosslinked with 1% by weight of polyallyl sucrose having 5.8 allyl groups per molecule (CARBOPOL 934 made by B. F. Goodrich Chemical Co., Akron, Ohio): 0.5

18 Hydroxyethyl cellulose: 0.5

19 Triethanolamine: 0.25

20 The gel is prepared by combining the hydrogen peroxide solution with the purified water, followed by the gradual addition of CARBOPOL 934. Upon thorough dispersion of the copolymer hydroxyethyl cellulose is slowly added and dissolved. Finally, triethanolamine is added, forming a clear, homogeneous, stable and viscous gel having a pH of 3.4.

21 EXAMPLE 2

22 Ingredients

23 Hydrogen peroxide, 35% aq. solution (3.5% H.sub.2 O.sub.2 in final gel): 10.0

parts

24 Distilled or deionized water: 88.9

25 Acrylic acid copolymer CARBOPOL 940 (Goodrich): 0.6

26 Hydroxyethylcellulose: 0.5

27 Sodium hydroxide, 10% solution: q.s. pH 3.8-4.0

28 Preparation: same as that of Example 1.

29 EXAMPLE 3

30 Ingredients

31 Hydrogen peroxide, 35% (3.5% H.sub.2 O.sub.2 in final gel): 10.0 parts

32 Distilled or deionized water: 89.0

33 Acrylic acid copolymer--CARBOPOL 941 (Goodrich): 0.7

34 Hydroxypropylcellulose: 0.3

35 Sodium hydroxide, 10% solution: q.s. pH 3.8-4.0

36 Preparation: same as that of Example 1.

37 EXAMPLE 4

38 Ingredients

39 Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel): 11.5 parts

40 Distilled or deionized water: 86.65

41 Acrylic acid copolymer--CARBOPOL 934 (Goodrich): 0.75

42 Sodium laurylsulfate, dentifrice grade: 0.50

43 Hydroxypropylcellulose: 0.6

44 Sodium hydroxide, 10% solution: q.s. pH 3.5-4.5

45 Preparation:

46 The hydrogen peroxide solution is combined with the distilled or deionized water. Sodium laurylsulfate is added under constant agitation and dissolved. Gradually, CARBOPOL 934 is added and dispersed. Hydroxypropylcellulose is added in increments and dissolved. When the mixture is homogeneous, sodium hydroxide is added slowly to the desired pH level and viscosity.

47 EXAMPLE 5

48 Ingredients

49 Hydrogen peroxide, 35% (6.0% H.sub.2 O.sub.2 in final gel): 17.14 parts

50 Distilled or deionized water: 81.76

51 Acrylic acid copolymer--CARBOPOL 940 (Goodrich): 0.70

52 Hydroxyethylcellulose: 0.40

53 Sodium hydroxide, 10% solution: q.s. pH 3.5-4.0

54 Preparation: same as that of Example 1.

55 EXAMPLE 6

56 Ingredients

57 Hydrogen peroxide, 35% (3.0% H.sub.2 O.sub.2 in final gel): 8.58 parts

58 Distilled or deionized water: 89.22

59 Acrylic acid copolymer--CARBOPOL 934 (Goodrich): 0.70

60 Hydroxypropyl methylcellulose: 0.65

61 Nonionic surfactant PLURONIC F 127 (BASF Corp., New Jersey): 0.85

62 Sodium hydroxide, 10% solution: q.s. pH 3.5-4.5

63 Preparation: same as that of Example 4.

64 EXAMPLE 7

65 The sodium bicarbonate paste is prepared as follows:

66 Ingredients

67 Deionized water: 31.94 parts

68 Sorbitol 70% solution, USP: 20.0

69 Cellulose gum--CMC 7MF (Hercules): 1.44

70 Sodium saccharin: 0.20

71 Magnesium aluminum silicate--VEEGUM F (made by R. T. Vanderbilt Co., Inc., Norwalk, Conn.): 1.17

72 Sodium bicarbonate, fine powder: 40.00

73 Sodium chloride: 4.00

74 Sodium lauryl sulfate--dentifrice grade: 0.30

75 Peppermint/Spearmint Flavor: 0.75

76 Methyl paraben, USP: 0.15

77 Propyl paraben, USP: 0.05

78 Procedure:

79 Glycerin and propylene glycol are combined in a first container with agitation. Cellulose gum is added and dispersed thoroughly throughout the mixture. Saccharin, methylparaben and propylparaben are added in a separate container and heated to dissolve. VEEGUM is added and the mixture is agitated until uniform. The contents of the first container are slowly added to the second

container and the final mixture is agitated thoroughly until uniform. Flavoring agent, sodium lauryl sulfate and coloring (if desired) are added and the paste is agitated at moderate speed until uniform. Further homogeneity may be obtained by milling, if necessary.

80 EXAMPLE 8

81 Ingredients

82 Deionized water: 33.43 parts

83 Glycerin: 10.00

84 Propylene glycol: 10.0

85 Cellulose gum--CMC 7MF (Hercules): 1.45

86 Sodium saccharin: 0.20

87 Magnesium aluminum silicate--VEEGUM F: 1.17

88 Sodium bicarbonate, fine powder: 25.00

89 Dicalcium phosphate dihydrate: 13.50

90 Dicalcium phosphate, anhydrous: 1.50

91 Sodium chloride: 2.50

92 Sodium lauryl sulfate, dentifrice grade: 0.30

93 Methylparaben, USP: 0.15

94 Propylparaben, USP: 0.05

95 Peppermint/Spearmint Flavor: 0.75

96 FD & C Blue No. 1, 0.1% solution: q.s

97 DS & C Yellow No. 6, 0.1% solution: q.s.

98 Procedure: Same as that of Example 8.

99 EXAMPLE 9

100 Paste containing fluoride:

101 Ingredients

102 Deionized water: 33.51

103 Sorbitol, 70% solution: 20.00

104 Sodium saccharin: 0.20

105 Cellulose gum CMC 7MF (Hercules): 1.54

106 Magnesium aluminum silicate--VEEGUM F: 1.17

107 Sodium fluoride: 0.33

108 Methyl paraben, USP: 0.15

109 Propyl paraben, USP: 0.05

110 Calcium sulfate: 10.00

111 Sodium bicarbonate: 25.00

112 Sodium chloride: 2.00

113 Hydrated aluminum oxide: 5.00

114 Peppermint/Spearmint Flavor: 0.75

115 Sodium lauryl sulfate: 0.30

116 Procedure: Same as that of Example 8.

117 EXAMPLE 10

118 Ingredients

119 Urea peroxide, 35% H.sub.2 O.sub.2 equivalent (5% H.sub.2 O.sub.2 in final gel): 14.3 parts

120 Purified water: 84.45

121 Copolymer of acrylic acid crosslinked with 1% by weight of polyallyl sucrose having 5.8 allyl groups per molecule (CARBOPOL 934 made by B. F. Goodrich Chemical Co., Akron, Ohio): 0.5

122 Hydroxyethyl cellulose: 0.5

123 Triethanolamine: 0.25

124 The gel is prepared by combining the hydrogen peroxide solution with the purified water, followed by the gradual addition of CARBOPOL 934. Upon thorough dispersion of the copolymer hydroxyethyl cellulose is slowly added and dissolved. Finally, triethanolamine is added, forming a clear, homogeneous, stable and viscous gel having a pH of 3.4.

CLAIMS:

What is claimed is:

1. A combination of a collapsible tube article having flexible side walls and a composition consisting of a gel component and a paste component and contained in said article, said combination being suitable for use in combatting gum disease, said article comprising:

(a) a first compartment containing said gel, said gel comprising (i) 1-10% by volume of hydrogen peroxide, (ii) 0.05-1.2% by volume of a water dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) 0.1-1.5% by volume of a non-ionic cellulose gum stabilizer (iv) purified water and (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in an amount sufficient to raise the pH of said gel to within about 3-6 such that the gel liquifies immediately upon contact with a mildly alkaline environment containing a strong electrolyte, thereby causing the release of bactericidally effective amounts of nascent oxygen; said gel having sufficient viscocity to support itself on the bristles of a toothbrush and sufficient fluidity to be dispensed from said flexible sidewall tube article upon squeezing; said first

compartment having an orifice for dispensing controlled amounts of said gel upon squeezing of said flexible sidewalls;

(b) a second compartment containing said paste, said paste comprising (i) 10-50% by weight of sodium bicarbonate; (ii) 1-6% by weight of a salt selected from the group consisting of NaCl and MgSO.sub.4 ; (iii) 1-3% by weight of a thickener-stabilizer selected from the group consisting of cellulose gum magnesium aluminum silicate, and mixtures thereof; (iv) 5-30% by weight of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol and polypropylene glycol, (v) purified water and (vi) 1-40% by weight of a cleansing-polishing agent selected from the group consisting of CaSO.sub.4, Ca.sub.3 (PO.sub.4).sub.2 and hydrated aluminum oxide, and (viii) 0.1-2.5% by weight of sodium lauryl sulfate; said paste having sufficient viscocity to support itself on the bristles of a toothbrush and sufficient fluidity to be dispensed from said flexible sidewall tube by squeezing, said second compartment having an orifice for dispensing controlled amounts of said paste upon squeezing of said flexible sidewalls substantially simultaneously with the dispensation of said gel in substantially equal amounts; said first compartment orifice and said second compartment orifice being adapted to dispense said gel and said paste respectively at the same use point, said first and second compartments having a common wall portion and said orifices being substantially adjacent; said article affording the following advantages over the use of an H.sub.2 O.sub.2, NaHCO.sub.3 and NaCl combination formed by dipping a toothbrush in a supply of H.sub.2 O.sub.2 followed by dipping said toothbrush in a paste consisting of NaHO.sub.3, NaCl and H.sub.2 O.sub.2 :

(i) ready availability of premeasured bactericidally effective amounts of active H.sub.2 O.sub.2 and NaHCO.sub.3 sufficient to combat gum disease and effective against bacterial plaque;

(ii) more vigorous release of said O.sub.2 due to the presence of said gel having a pH of about 3-6 on one hand and the presence of NaHCO.sub.3, which is alkanine, and NaCl, which is a strong electrolyte, on the other hand;

(iii) improved penetration into gum tissues of nascent oxygen NaHCO.sub.3 and NaCl and more intimate contact with tooth and gum surfaces; and

(iv) substantially smoother texture and a more palatable and pleasant taste.

2. The article of claim 1 wherein said first and second compartments are substantially equivolumetric parts of a single collapsible tube having one orifice, divided into said compartments by a divider, said divider extending into said orifice.

3. The article of claim 1 wherein said gel component comprises 3-6.5% H.sub.2 O.sub.2, 0.3-0.8% acrylic acid copolymer and 0.3-0.8% nonionic cellulose gum stabilizer and wherein said paste component comprises 20-40% sodium bicarbonate, 2-4% NaCl, 1.2-1.8% of said thickener-stabilizer, 15-25% of said humectant, and wherein said paste component further comprises: from zero to about 1% by weight of a flavoring agent selected from the group consisting of artificial sweeteners, spearmint flavor, peppermint flavor, cinnamon flavor, citrus flavor and mixtures thereof; and 0.1-0.5% by weight of a member of the group consisting of methylparaben, propyl paraben and mixtures thereof.

4. The article of claim 3, wherein said gel cellulose gum stabilizer is hydroxypropylcellulose, said neutralizing agent is sodium hydroxide, said paste thickener-stabilizer is a mixture of cellulose gum and magnesium aluminum silicate, said humectant is sorbitol and said cleansing-polishing agent is calcium sulfate.

5. A method of combating gum disease comprising substantially simultaneously dispensing the gel and paste of the article according to claim 1 by squeezing the flexible sidewalls of said article.

6. The composition of claim 1, wherein said paste component also contains a fluoride compound effective against caries, said composition being suitable as a toothpaste substitute also effective against gum disease.

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L2: Entry 1 of 1 File: USPT Aug 18, 1987

US-PAT-NO: 4687663
DOCUMENT-IDENTIFIER: US 4687663 A

TITLE: Dental preparation, article and method for storage and delivery thereof

DATE-ISSUED: August 18, 1987

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Schaeffer; Hans A.	Linden	NJ	07036	

APPL-NO: 06/ 745993 [PALM]
DATE FILED: June 17, 1985

PARENT-CASE:
This is a continuation-in-part, of application Ser. No. 737,157 filed 5/23/85, abandoned which in turn is a continuation-in-part of appln. Ser. No. 471,188, filed 3/1/83 now U.S. Pat. No. 4,528,180.

INT-CL: [04] A61K 7/16, A61K 7/18, A61K 7/20

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US-CL-CURRENT: 424/52; 222/1, 222/137, 222/94, 424/49, 424/53, 514/835, 514/900, 514/902, 514/944

FIELD-OF-SEARCH: 222/1, 222/94, 424/49, 424/52, 424/53, 514/835, 514/900, 514/902, 514/944

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

Search Selected Search ALL

PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
2905364	September 1959	Marrafino	222/94
2914220	November 1959	Marrafino	222/94
3175731	March 1965	Ellman	222/94
4528180	July 1985	Schaeffer	424/52

ART-UNIT: 125

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

Disclosed is a method for cleaning teeth including extruding a first semi-solid component including hydrogen peroxide as an active ingredient, and extruding a second semi-solid component comprising sodium bicarbonate as an active ingredient, the first and second components being suitable for oral use. The first component and the second component are placed in contact with each other on a toothbrush. The teeth are brushed using the first and second components concurrently as a cleaning medium.

17 Claims, 7 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 4

BRIEF SUMMARY:

1 This invention relates to a dental preparation useful in the treatment of gum disease, to a method of storing and delivering such preparation to a use point and to an article for the storage and delivery of such preparation.

2 It has long been recognized that the combination of hydrogen peroxide solution with sodium bicarbonate and table salt has an excellent curative and preventive effect on gum disease caused by bacterial infection. Dr. Paul H. Keyes has advocated use of this combination to the dental profession and to the public at large based on his work of more than 25 years on the subject, which has shown that upon daily and diligent topical application of these materials, gum disease may be effectively controlled. On the basis of his recommendations, many dentists urge their patients to use the Keyes procedure (substantially as described e.g. in S. Elder: "An Alternative To Gum Surgery" Modern Maturity, August-September 1980 pp. 31-32).

3 Dr. Keyes advocates that a quantity of solid sodium bicarbonate be placed in one hand, and that the toothbrush, held in the other hand, be dipped into a hydrogen peroxide-table salt solution and then transferred to the bicarbonate and applied to the teeth and gums. Upon contact with the gums, the hydrogen peroxide is exposed to the enzyme catalase, which is always present in the buccal cavity, and is attacked thereby resulting in the release of active oxygen. The combination of the active oxygen and the sodium bicarbonate together with table salt destroys the bacteria responsible for gum desease. Unfortunately, hydrogen peroxide and sodium bicarbonate may not be premixed, as they immediately react and are thereby rendered ineffective against gum desease. In addition, hydrogen peroxide is unstable and therefore difficult to store for prolonged periods of time. Finally, mere dipping of the toothbrush in a hydrogen peroxide solution does not insure delivery of a sufficient amount of hydrogen peroxide to the teeth and gums. These factors are responsible for the fact that use of the Keyes procedure is extremely awkward, inconvenient and messy. Another disadvantage stems from the fact that, the mixture of hydrogen peroxide and sodium bicarbonate has a very unpleasant taste. For these reasons, patients have shown extreme reluctance to follow this procedure, especially on a daily basis, as would be required for effective gum desease control. As a result, the benefits which the Keyes procedure affords have largely been left unrealized.

4 Accordingly, it is an object of this invention to eliminate the above disadvantages associated with use of the Keyes procedure by providing a dental preparation incorporating the active constituents of the Keyes procedure that has pleasant taste and is neat and convenient to use, and a method for using such preparation that permits contact between hydrogen peroxide and sodium bicarbonate only shortly before use and, therefore, assures maximum effectiveness against gum disease.

5 It is another object of the present invention to provide a dental preparation incorporating the active constituents of the Keyes method and a method for using such preparation that permits a sufficient, consistent and reproducible amount of hydrogen peroxide to be delivered to the use point.

6 It is yet another object of this invention to provide an article for the storage and delivery of this improved dental preparation which makes its use neat and convenient and which prevents contact between hydrogen peroxide and sodium bicarbonate prior to application.

7 In accordance with the present invention, hydrogen or urea peroxide is dissolved in a nontoxic gel for use in combination with a separately stored but substantially simultaneously dispensed paste containing sodium bicarbonate, table (or another suitable) salt, and, preferably, additional cleansing, anticaries and polishing agents as well as an effective concentration of flavoring substances. Each of the gel and paste are loaded either into separate collapsible containers which are connected by means of a common orifice (as in FIG. 1), or which have substantially adjacent orifices (as in FIG. 2), or in separate compartments of a single container (as in FIGS. 3 or 4). Alternatively, the gel and paste may be loaded in separate compartments of a two-compartment pressurized container (as in FIG. 5) or a mechanically actuated pump, as in FIG. 6.

8 Upon substantially simultaneous squeezing of the containers, in much the same way as common toothpaste tubes (or upon actuating of the pressurized container or pump), controlled quantities of the gel and paste can be simultaneously released onto the toothbrush and immediately applied to the teeth and gums. Control of the peroxide, salt, and NaHCO.sub.3 quantities delivered may be thus effected by specification of the opening of the orifice and the active ingredient concentration in each tube (or pump compartment). As described above, when the brush is applied to teeth and gums, immediate mixing of the products takes place followed by the rapid evolution of active oxygen and carbon dioxide. At the same time, the effervescence accompanying release of active oxygen activates the flavor contained in the bicarbonate paste and produces a lasting highly refreshing taste in the mouth which is unlike any other flavor provided by existing toothpastes or gels.

9 Another advantage afforded by the present invention, as compared with the Keyes procedure, is that a greater and more consistent amount of peroxide is delivered to the use point.

10 Yet another advantage stems from the tendency of the present composition to cling to the gum tissues and thus provide them with the full benefit of substantially all of the composition applied to the gums.

11 Gelling agents suitable for use in preparation of the peroxide gel in accordance with this invention should be nontoxic and neutral to the peroxide to assure its stability. In addition, they should be preferably sensitive to external electrolytes, such as those contained in the sodium bicarbonate paste, in order to make peroxide immediately available to the oral tissues. A gelling agent suitable for use with the present invention is a copolymer of acrylic acid cross-linked with polyallyl sucrose, as described in U.S. Pat. No. 2,798,053 issued on July 2, 1957 and assigned to B. F. Goodrich Inc. Other gelling agents resulting in stable hydrogen (or urea) peroxide gels suitable for use in the present invention include those described in British Pat. No. 827,331, i.e., organic polymeric acid colloids including polyuronic acids, carboxypolymethylene compounds and polyester resins containing three carboxyl groups, such as partially hydrolized polyacrylates or polymethacrylates and copolymers thereof; and those described in U.S. Pat. No. 3,639,574 issued on Feb. 1, 1972 to Schmolka, i.e., polyoxyethylene polyoxypropylene block copolymers, which, according to Schmolka, may be used in the preparation of stable, firm hydrogen peroxide gels. Preferred are water-dispersible copolymers of acrylic acid cross-linked with about 0.75 to about 1.5% of polyallyl sucrose and neutralized with triethanolamine, NaOH or another alkalizing agent, as taught in U.S. Pat. No. 3,499,844.sup.1 issued on Mar. 10, 1970 to Kibbel et al. For purposes of the present invention, Kibbel's acrylic copolymer may be preferably combined with an anionic or non-ionic surfactant, such as disclosed in U.S. Pat. No. 4,130,501.sup.2 issued on Dec. 19, 1978 to Lutz et al. Such surfactants are not essential for the formation of a stable hydrogen peroxide

gel in accordance with this invention, but may be added to facilitate distribution and rapid penetration of the active oxygen throughout the area to be treated. A particularly preferred gelling agent for the purposes of the present invention is that described by Kibbel, supra. This gelling agent may but does not have to be modified by the addition of a suitable amount of non-ionic cellulose gum such as hydroxyethyl- or hydroxypropyl-cellulose or hydroxypropyl-methyl-cellulose in order to improve the physical stability of the gel, especially when subjecting it to stress such as that resulting from squeezing of the collapsible tubes, or pumping action.

1 .sup.1 The disclosures of these patents are incorporated herein by reference.

2 .sup.2 The disclosures of these patents are incorporated herein by reference.

12 The most preferred gelling agents are marketed under the trademark CARBOPOL 941 or 1342 by Goodrich. Carbopol 941 does not need neutralization for gelling (and preferably is not neutralized in this invention) because it gels readily in the presence of hydrogen donors. Carbopol 941 has proved to have greater long term physical stability (also believed to be due to hydrogen bonding). Although Carbopol 1342 has just become available on the market and its composition and characteristics have not been fully disclosed, it is claimed by the manufacturer that this acrylic acid copolymer (even though it needs to be neutralized) displays satisfactory long term stability comparable to that of Carbopol 941.

13 Gels made from these agents do not need any cellulose additive as a stabilizer, because they are thixotropic (and also pseudoplastic).

14 Not only is Carbopol 941 the most preferred gelling agent for non-neutralized gels, it is also most preferred for neutralized gels along with Carbopol 934, 940 and 1342.

15 The hydrogen peroxide gel may then contain the following ingredients in the following amounts--H.sub.2 O.sub.2 : about 0.1-10.0% and preferably about 3.0-6.5%; Acrylic acid copolymer: about 0.05-5.0% and, preferably, about 1.0-3.0%; nonionic cellulose gum (optional): about 0-2.0% and, preferably, about 0.3-1.5%; neutralizing agent (triethanolamine, diisopropanolamine, NaOH, KOH): an amount sufficient to raise the gel pH to about 3.0-6.0; NaOH is preferred. The balance is purified (distilled or deionized) water.

16 If a non-neutralized gelling agent is used, the aforementioned gel may contain about 2-80% and preferably about 20-60% by weight of a polyol selected from the group consisting of glycerin, sorbitol (70% solution) polypropylene glycol, propylene glycol, polyethylene glycol, ethoxylated or propoxylated lower (C.sub.2 -C.sub.5) fatty alcohols and mixtures thereof. The preferred polyol is glycerin. The amount of the water is decreased so that the total adds up to 100% by weight. The pH need not be controlled but falls between about 2 and 4.

17 The sodium bicarbonate paste contains sodium bicarbonate, sodium chloride (or another suitable salt although the salt may be omitted, if desired), purified (distilled or deionized) water, a thickener/stabilizer such as cellulose gum and or magnesium-aluminum silicate, as essential ingredients and, most preferably, it also contains a polishing/stabilizing agent, such as bentonite, silica, titanium dioxide, magnesium oxide or mixtures thereof (the first three and their mixtures are preferred). In order to disperse the "chalky" taste imparted mostly by the bicarbonate and enhance the taste and plasticity of the paste, a bodying agent is added, such as sorbitol, glycerin and/or a glycol. In addition, if the paste (in combination with the gel) is to displace toothpaste completely, additional cleansing agents, such as calcium sulfate, calcium phosphate, hydrated aluminum oxide, calcium carbonate, magnesium carbonate, and magnesium silicate or mixtures thereof can be added. A fluorine-containing compound is also preferably included for its anti-caries activity. Suitable fluorine-containing compounds are NaF, Na-monofluorophosphate, KF, potassium monofluorophosphate, sodium fluorosilicate, sodium fluorozirconate, etc. (with

NaF being most preferred). Finally, a foaming agent such as sodium lauryl sulfate (most preferred), sodium N-lauroyl sarcosinate, sodium coconut monoglyceride sulfonate, sodium N-methyl-N-palmitoyl lauride or a nonionic surfactant such as a polysorbate (e.g. Tween 60 or 80 manufactured by ICI Americas, Wilmington, Del.) or poloxamer or mixtures thereof, which also enhances the peroxide-bicarbonate-salt action, may be added. Flavoring agents, such as sodium saccharin, or other artificial sweeteners, peppermint or spearmint or other flavors are preferably added to further curb the unpleasant taste. Finally, methyl, butyl and/or propyl paraben, sodium benzoate, potassium sorbate or mixtures thereof are preferably added as preservatives, with methyl and propylparaben being most preferred. Use of a coloring agent is optional.

18 The constituents and quantities for the bicarbonate paste are as follows:

19 sodium bicarbonate: about 2-60% and preferably 20-40%;

20 salt: about 0-6%, preferably about 1-6% and most preferably about 2-4% of NaCl (preferred) or KCl, MgCl.sub.2, MgSO.sub.4, Na.sub.2 SO.sub.4 or K.sub.2 SO.sub.4 or mixtures thereof;

21 humectant: about 2-60% and preferably, 15-25% consisting of glycerin, sorbitol propylene glycol, polyethylene glycol, polypropylene glycol, ethoxylated or propoxylated lower fatty alcohols and mixtures thereof;

22 thickener-stabilizer: nonionic cellulose gum--about 0.1-5% and preferably 1.0-2.0%; or magnesium aluminum silicate or mixtures thereof in the same proportions;

23 stabilizer/polishing agent/cleanser: total about 1-30%, preferably about 1.5-20%; these preferably include one or more of: bentonite--about 0.5-7.5%; silica--about 0.1-8.0%; titanium dioxide--about 0.1-8.0%; and/or magnesium oxide--about 0.2-8.0%; preferably, about 1.5-5.0; 0.5-6.0; 0.5-3.0; and 0.5-3.0 percent, respectively.

24 fluorine-containing compound: sufficient to yield 200 to 3,000 ppm and preferably 1,000 to 2,000 ppm fluorine;

25 foaming agent: about 0.1-2.5%; preferably about 0.2-0.5%;

26 additional polishing agents: total about 1-30%, preferably about 5-20%;

27 flavoring agent(s): to taste, preferably 0.1-2%;

28 preservatives: about 0.05-0.5%.

29 The balance is purified water. A coloring agent may be added. The paste and the gel are preferably used in substantially equal proportions, by volume.

30 If urea peroxide is used in the gel, the bicarbonate paste composition does not change. The gel composition will be as follows:

31 urea peroxide: about 2-25%, preferably about 8-12%;

32 acrylic copolymer: about 0-3.5, preferably about 1-3%;

33 glycerin: balance.

34 The other polyols described above are reactive with the urea peroxide and should not be used.

DETAILED DESCRIPTION:

1 The gel and paste combination may be simultaneously dispensed from separate collapsible tubes preferably made of plastic, or a plastic/metal laminate (to avoid reaction with H.sub.2 O.sub.2) and enhanced flavor retention), such as tubes 1 and 2 shown in FIG. 1. The tubes are fitted with a Y-shaped conduit 3 which provides them with a common orifice 6. Conduit 3 may also be made of plastic (preferably by injection molding) and is preferably detachably but snugly attached to mouths 4,5 of tubes 1,2 so that it may be removed for cleaning. For additional convenience and in order to ensure dispensation of substantially equal amounts of the gel and paste, the tubes themselves may be held together, e.g., by banding or cementing, along corresponding dorsal sides, shown in FIG. 1, or, preferably, along corresponding ventral sides (see, e.g., FIG. 3A).

2 Alternatively, the two tubes may be constructed to have a common (preferably flat) sidewall portion 26 as shown in FIG. 2. In the latter case, the Y-shaped conduit may be unnecessary, if the mouths 24,25 of tubes 21,22 are sufficiently close so that sufficient quantities of the gel and paste may be simultaneously dispensed directly on the toothbrush. Conventional toothpaste or medicament tubes may be thus used after one of their side walls and the corresponding portion of their head structure are permanently deformed (e.g. by application of pressure) to a substantially flat surface.

3 A third alternative packaging method involves loading each of the gel and paste into separate compartments of the same collapsible tube, joined by a common orifice, as shown in FIG. 3. Composite tube 31 has compartments 32, 33 separated by divider 34 which is firmly attached along substantially diametrically opposed portions 35,36 of the sidewall 37, and corresponding portions 38,39 of head structure 40. Divider 34 may be glued or welded to sidewall 37 and head structure 40 of tube 31 during manufacture of the latter. Divider 34 is preferably provided with protruding portion 41, which extends into the mouth 42 of tube 31 until its edge is substantially flush with rim 43 of mouth 42. Thus, divider 34 forms with sidewall 37 two separate compartments 32,33 of substantially the same volume for storage of the gel and paste, respectively.

4 In another alternative packaging method, the two tubes are "concentric" as shown in FIG. 4A. Inner tube 401 lies within and parallel with outer tube 402.

5 The mouths of the tubes 401 and 402, designated as 405 and 404 in FIG. 4, abut at the same point. Tube 401 is fastened on to tube 402 at the mouth by protrusion 406 (shown in enlargement in FIG. 4B, which is a cross-section of the embodiment of FIG. 4A taken along 4B--4B). Protrusions 406 are inserted in a groove of mouth 404 of tube 402. The material contained in tube 402 can still pass through the available space between mouth 404 of outer tube 402 and mouth 405 of inner tube 401. Engagement of pins 406 in the groove secures the inner tube 401 on the outer tube 402.

6 The closure 407 of the tube-within-a-tube (which can screw on the outer tube or simply be held by pressure) arrangement may but does not have to be equipped with an interior protrusion 408 to fit in the inner tube in order to prevent premature intermixing of the two components at the mouth of the tube. Because of the pseudoplastic quality of the gel and/or the memory of the plastic tube, however, such intermixing is not likely to occur. The tubes are filled from the bottom and are (subsequently) sealed together by conventional techniques.

7 Other alternative packaging arrangements are disclosed in FIGS. 5 and 6. Pressurized container 501 in FIG. 5 is provided with two compartments 502 and 503 and two spouts 504 and 505. The internal pressure of the compartments is maintained by pressurized nitrogen, at the bottom 506 of each compartment. Operation of the mechanical actuator 507 (by pressing downwards) actuates valves 508 and 509 which release the contents of the compartments through the spouts (channels) causing the upwardly slidable sealing disks 510 and 511 (guided by members 512, 513) to move up along the compartments (due to the

nitrogen being under pressure). Similar (but conventional) pressurized containers are manufactured for example by American Can Company. A dual compartment container, as described above, would be a modification of the existing containers.

8 In an alternative pump embodiment depicted in FIGS. 6 and 7 a pressurized container 601 is provided with two compartments 602 and 603, and two spouts 604 and 605 for dispensing the gel and paste. Located within the tube 605 is a first piston 606 which is held in place by the upper surface of the contents within compartment 603 and a tubular extension 607 fitting within the lower portion of spout 605. A spring 608 is under compression and is held in position by the upper conical surface 609 of piston 606 and an inner shelf 610 of the spout 605. Lower pistons 611 and 612 are positioned within the lower portions of compartments 602 and 603 respectively so as to follow the dental material upwardly as it is being dispensed into the spouts 604 and 605 and eventually into nozzle 613. The upper part of container 601 has a reduced diameter to encircle the nozzle 613 and provide for a sliding engagement. Outer cap member 614 is threadedly engaged as at 615, with outer surface of nozzle 613 to effectively seal the container and prevent inadvertent dispensing of dental material as well as a pin 616 which fits snugly into open end of nozzle 613.

9 In operation, and with cap 614 removed, the user will depress a push button lever 617 (seen in FIG. 7) located outside the container 601. Lever 617 has substantially flat elongated member 618 which projects between spouts 604 and 605 and presses against wall 619 which bridges both spouts. Lever 617 is pivoted about pivot pin 620 affixed to inner wall of container 601. As lever 617 is depressed, member 618 will force spouts 604 and 605 downwardly and subsequently spring 608 as well as piston 606 will be lowered to phantom position (as seen in FIG. 6) causing dental material to flow upwardly within extension 607 and spout 605, mixing with material in spout 604 and through nozzle 613 to the bristles of a toothbrush. As the lever is released, the spring 608 will force nozzle 605 upwardly to its original position against conical portion 621 of container 601. The vacuum created will cause piston 606 to raise upwardly and concomitantly cause lower piston 612 to travel upwardly the distance of the expelled dental material. A spring clip 621 slideably engages inner surface of compartment 603 to allow piston to travel upwardly but be prevented from movement downwardly. Description of compartment 602 and spout 604 with its accompanying component parts operate in a like manner as described above.

10 The particular packaging arrangement used is not important. Those skilled in the art will be able to fashion several obvious modifications of the containers described herein by way of illustration.

11 Tubes, such as those suitable for use in accordance with the present invention are usually extruded around a cylindrical mandrel, cut into tube segments of suitable length, fitted with head structures and then filled from the bottom and pressed and/or welded closed, substantially as described in, e.g., U.S. Pat. No. 4,060,179 issued on Nov. 29, 1977 to McGhie, the disclosure of which is incorporated herein by reference.

12 In the case of the tube-within-a-tube embodiment of the present invention, the outer tube is provided first but it is not closed at the end opposite to that of the closure. The inner tube (also open-ended at the corresponding end) is inserted and fastened to the mouth of the outer tube. The two tubes are then filled and sealed together. A similar tube-within-a-tube arrangement has been proposed and described in U.S. Pat. No. 1,566,218 of Leland and issued on Dec. 15, 1925, incorporated here by reference.

13 The invention is further illustrated by the following specific examples which are designed merely to illustrate the present invention and not to limit its scope.

14 In these examples, a hydrogen peroxide gel containing 3-6.5% hydrogen peroxide

by weight, useful for simultaneous administration with a sodium bicarbonate paste is prepared as follows:

15 EXAMPLE 1

16 Ingredients

Hydrogen peroxide, 35% aqueous solution (5% H.sub.2 O.sub.2 in final gel)	14.3 parts
Purfied water	84.45
Copolymer of acrylic acid crosslinked with 1% by weight of polyallyl sucrose having 5.8 allyl groups per molecule (CARBOPOL 934 made by B. F. Goodrich Chemical Co., Akron, Ohio)	0.5
Hydroxyethyl cellulose	0.5
Triethanolamine	0.25

17 The gel is prepared by combining the hydrogen peroxide solution with the purified water, followed by the gradual addition of CARBOPOL 934. Upon thorough dispersion of the copolymer hydroxyethyl cellulose is slowly added and dissolved. Finally, triethanolamine is added, forming a clear, homogeneous, stable and viscous gel having a pH of 3.4.

18 EXAMPLE 2

19 Ingredients

Hydrogen peroxide, 35% aq. solution (3.5% H.sub.2 O.sub.2 in final gel)	10.0 parts
Distilled or deionized water	88.9
Acrylic acid copolymer CARBOPOL 940 (Goodrich)	0.6
Hydroxyethylcellulose	0.5
Sodium hydroxide, 10% solution	q.s. pH 3.8-4.0

20 Preparation: same as that of Example 1.

21 EXAMPLE 3

22 Ingredients

Hydrogen peroxide, 35% (3.5% H.sub.2 O.sub.2 in final gel)	10.0 parts
Distilled or deionized water	

	89 0
Acrylic acid copolymer - CARBOPOL 941 (Goodrich	0.7
Hydroxypropylcellulose	0.3
Sodium hydroxide, 10% solution	q.s. pH 3.8-4.0

23 Preparation: same as that of Example 1.

24 EXAMPLE 4

25 Ingredients

Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5 parts
Distilled or deionized water	86.65
Acrylic acid copolymer - CARBOPOL 934 (Goodrich)	0.75
Sodium laurylsulfate, dentifrice grade	0.50
Hydroxypropylcellulose	0.6
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.5

26 Preparation:

27 The hydrogen peroxide solution is combined with the distilled or deionized water. Sodium laurylsulfate is added under constant agitation and dissolved. Gradually, CARBOPOL 934 is added and dispersed. Hydroxypropylcellulose is added in increments and dissolved. When the mixture is homogeneous, sodium hydroxide is added slowly to the desired pH level and viscosity.

28 EXAMPLE 5

29 Ingredients

Hydrogen peroxide, 35% (6.0% H.sub.2 O.sub.2 in final gel)	17.14 parts
Distilled or deionized water	81.76
Acrylic acid copolymer - CARBOPOL 940 (Goodrich)	0.70
Hydroxyethylcellulose	0.40
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.0

30 Preparation: same as that of Example 1.

31 EXAMPLE 6

32 Ingredients

Hydrogen peroxide, 35% (3.0% H_2O_2 in final gel)	8.58 parts
Distilled or deionized water	89.22
Acrylic acid copolymer - CARBOPOL 934 (Goodrich)	0.70
Hydroxypropyl methylcellulose	0.65
Nonionic surfactant PLURONIC F 127 (BASF Corp., New Jersey)	0.85
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.5

33 Preparation: same as that of Example 4.

34 EXAMPLE 7

35 The sodium bicarbonate paste is prepared as follows:

36 Ingredients

Deionized water	31.94 parts
Sorbitol 70% solution, USP	20.0
Cellulose gum - CMC 7MF. (Hercules)	1.44
Sodium saccharin	0.20
Magnesium aluminum (made by R. T. Vanderbilt Co., Inc., Norwalk, Conn.)	1.17
Sodium bicarbonate, fine powder	40.00
Sodium chloride	4.00
Sodium lauryl sulfate - dentifrice grade	0.30
Peppermint/Spearmint Flavor	0.75
Methylparaben, USP	0.15
Propylparaben, USP	0.05

37 Procedure:

38 Glycerin and propylene glycol are combined in a first container with agitation. Cellulose gum is added and dispersed thoroughly throughout the mixture. Saccharin, methylparaben and propylparaben are added to the required amount of

purified water in a separate container and heated to dissolve. VEEGUM is added and the mixture is agitated until uniform. The contents of the first container are slowly added to the second container and the final mixture is agitated thoroughly until uniform. Flavoring agent, sodium lauryl sulfate and coloring (if desired) are added and the paste is agitated at moderate speed until uniform. Entrapped air is removed by degassing in a vacuum vessel. Further homogeneity may be obtained by milling, if necessary.

39 EXAMPLE 8

40 Ingredients

Deionized water	33.43	parts
Glycerin	10.00	
Propylene glycol	10.0	
Cellulose gum - CMC 7MF (Hercules)	1.45	
Sodium saccharin	0.20	
Magnesium aluminum silicate - VEEGUM F	1.17	
Sodium bicarbonate, fine powder	25.00	
Dicalcium phosphate dihydrate	13.50	
Dicalcium phosphate, anhydrous	1.50	
Sodium chloride	2.50	
Sodium lauryl sulfate, dentifrice grade	0.30	
Methylparaben, USP	0.15	
Propylparaben, USP	0.05	
Peppermint/Spearmint Flavor	0.75	
FD & C Blue No. 1, 0.1% solution	q.s.	
DS & C Yellow No. 6, 0.1%	solution q.s.	

41 Procedure: Same as that of Example 8

42 EXAMPLE 9

43 Paste containing fluoride:

44 Ingredients

Deionized water	33.51
Sorbitol, 70% solution	20.00
Sodium saccharin	0.20
Cellulose gum CMC 7MF (Hercules)	1.54
Magnesium aluminum silicate - VEEGUM F	1.17
Sodium fluoride	0.33
Methylparaben, USP	0.15
Propylparaben, USP	0.05

Calcium sulfate	10.00
Sodium bicarbonate	25.00
Sodium chloride	2.00
Hydrated aluminum oxide	5.00
Peppermint/Spearmint Flavor	0.75
Sodium lauryl sulfate	0.30

45 Procedure: Same as that of Example 8.

46 EXAMPLE 10

47 Peroxide Gels

Composition 10-A	
Hydrogen peroxide, 35% aqueous solution (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	86.6
Acrylic acid copolymer - Carbopol 934 (Goodrich)	1.5
Sodium lauryl sulfate, dentifrice grade	0.1
Hydroxypropyl cellulose	0.3
Sodium hydroxide, 10% solution	q s. pH 3.0-4.5
Composition 10-B	
Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	88.0
Acrylic acid copolymer (Carbopol 934, 940, 941, or 1342)	1.5
Sodium hydroxide, 10% solution	q.s. pH 3.0-4.5
Composition 10-C	
Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	46.0
Glycerin, anhydrous	40.0
Acrylic acid copolymer - Carbopol 941	2.5

48 Methods of preparation

49 Composition 10-A: same as listed in Example 4

50 Composition 10-B: same as in Example 4 except that sod. lauryl sulfate and hydroxypropyl cellulose were omitted. The composition including Carbopol 1342 has not been actually made.

51 Composition 10-C: The glycerin and water were combined and heated to 50.degree.-60.degree. C. Very slowly, Carbopol 941 was added under constant agitation.

52 When a clear gel had formed and no undissolved lumps remained, the gel was

cooled to 25.degree. C. and the hydrogen peroxide was added. Agitation was maintained until the mixture became homogeneous. The gel was de-aerated in a vacuum vessel.

53 EXAMPLE 11

54 Sodium bicarbonate Paste

Composition 11-A	
Glycerin	25.0
Cellulose gum CMC 7MF (Hercules)	1.54
Deionized water	32.71
Magnesium aluminum silicate Veegum (R. T. Vanderbilt)	1.10
Sodium saccharin	0.60
Sodium chloride	2.0
Methylparaben	0.15
Propylparaben 0.05	
(Sodium hydroxide solution 10%, q.s. pH 8.0-8.5, may be added, if necessary for pH adjustment)	
Sodium fluoride	0.22
Bentonite	4.0
Titanium dioxide	2.0
Silica	4.0
Sodium bicarbonate	25.0
Flavor (spearmint)	1.0
Sodium lauryl sulfate	0.3
Color (FDC Blue No. 1) q.s.	

55 Method of preparation

56 The cellulose gum was added to the glycerin and dispersed thoroughly.

57 In a separate vessel, the parabens, sodium saccharin, and sodium chloride were dissolved in water at 60.degree.-70.degree. C. To the clear solution was added the Veegum and the mixture was agitated until uniform. The pH of this solution was determined to be 8.0-8.5 (and adjusted, if necessary).

58 The gum dispersion was added to the Veegum solution and agitated until uniform.

59 To the blend were added the powders, bentonite, TiO.sub.2, silica, NaHCO.sub.3, and NaF, under vigorous agitation.

60 To the paste were added flavor, sodium lauryl sulfate and color.

61 The finished paste is milled and degassed in a vacuum vessel.

62 EXAMPLE 13

63 Urea peroxide gel

Composition 13-A

Urea peroxide (35% H.sub.2 O.sub.2 equivalent)	10.0	parts by weight
Glycerin, anhydrous	90.0	

64 Method: Urea peroxide is slowly added under agitation to the anhydrous glycerin until a clear gel is formed which has a suitable consistency for filling into collapsible tubes.

Composition 13-B	
Urea peroxide	10.0
Acrylic acid copolymers - Carbopol 941	1.5
Glycerin, anhydrous	88.5

65 The method is the same as that for 13-A except the urea peroxide and Carbopol 941 are both added to the glycerin solution.

66 Although the present invention has been described with reference to preferred embodiments, those of ordinary skill in the art will readily appreciate that many additions, deletions, modifications and substitutions are possible within the spirit of the present invention and the scope of the following claims.

CLAIMS:

What is claimed is:

1. A method for cleaning teeth comprising extruding a first semi-solid component comprising hydrogen peroxide as an active ingredient, said first component being suitable for oral use;

extruding a second semi-solid component comprising sodium bicarbonate as an active ingredient, said second component being suitable for oral use;

placing said first component and said second component in contact with each other on a toothbrush; and

brushing said teeth using said first and second components concurrently as a cleaning medium.

2. The method of claim 1, wherein said first and second components are extruded together.

3. The method of claim 1, wherein said first and second components are extruded together on the toothbrush.

4. The method of claim 1, wherein said first and second components are extruded and placed on the brush separately.

5. The method of claim 1, wherein said brushing takes place immediately after extruding said components and placing them onto said toothbrush.

6. The method of claim 1, wherein said first component contains from about 0.1 to about 10 percent H.sub.2 O.sub.2.

7. The method of claim 1, wherein said first component is a non-neutralized

gel.

8. The method of claim 1, wherein said first component is a neutralized gel.

9. The method of claim 1, wherein said second component contains from about 2 to about 60 percent sodium bicarbonate by weight.

10. The method of claim 1, wherein said second component is a paste.

11. The method of claim 1, wherein said first component is a gel comprising as a gelling agent a member selected from the group consisting of (a) copolymers of acrylic acid cross-linked with polyallyl sucrose; (b) an organic polymeric acid colloid; and (c) a polyoxyethylene/polyoxypropylene block copolymer.

12. The method of claim 1, wherein said second component is a paste comprising a thickener/stabilizer.

13. The method of claim 12, wherein said paste component further comprises a bodying agent.

14. The method of claim 12, wherein said paste component further comprises an additional tooth-cleaning agent.

15. The method of claim 12, wherein said paste component further comprises a fluorine-containing compound having anti-caries activity.

16. The method of claim 7, wherein said gel component further comprises a copolymer of acrylic acid cross-linked with polyallyl sucrose as a gelling agent.

17. The method of claim 8, wherein said gel component further comprises a copolymer of acrylic acid cross-linked with polyallyl sucrose as a gelling agent and a polyol selected from the group consisting of glycerin, sorbitol, propylene glycol, polypropylene glycol, polyethylene glycol, an ethoxylated lower fatty alcohol and a propoxylated lower fatty acid alcohol.

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L3: Entry 1 of 1 File: USPT Jul 18, 1989

US-PAT-NO: 4849213
DOCUMENT-IDENTIFIER: US 4849213 A

TITLE: Dental preparation, article and method for storage and delivery therof

DATE-ISSUED: July 18, 1989

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Schaeffer; Hans A.	Linden	NJ	07036	

DISCLAIMER DATE: 20020709

APPL-NO: 07/ 064880 [PALM]
DATE FILED: June 19, 1987

PARENT-CASE:
This application is a divisional application of U.S. application Ser. No. 745,993, filed June 17, 1985 (now U.S. Pat. No. 4,687,663, the full disclosure of which is incorporated herein by reference), which was a continuation-in-part application of U.S. application Ser. No. 737,157, filed May 23, 1985 (now abandoned), which in turn was a continuation-in-part application of U.S. application Ser. No. 471,188, filed Mar. 1, 1983 (now U. S. Pat. No. 4,528,180 the full disclosure of which is incorporated herein by reference).

INT-CL: [04] A61K 7/20, A61K 33/40

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US-CL-CURRENT: 424/53; 424/616

FIELD-OF-SEARCH: 424/499, 424/253, 424/53, 424/130

PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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ART-UNIT: 125

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

A composition useful in combatting gum disease including:

(a) a gel component including (i) about 0.1-10% by weight of hydrogen peroxide; (ii) about 0.05-5.0% by weight of a water-dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) about zero to about 2.0% by weight of a nonionic cellulose stabilizer; (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in an amount sufficient to raise the gel pH to about 3-6.0; and (v) purified water;

(b) a paste component including (i) about 2-60% sodium bicarbonate; (ii) about 1-6% of a salt selected from the group consisting of NaCl, MgCl.sub.2, MgSO.sub.4, Na.sub.2 SO.sub.4, and K.sub.2 SO.sub.4 ; (iii) about 2-60% of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol, propylene glycol, polypropylene glycol, an ethoxylated lower fatty alcohol, a propoxylated lower fatty alcohol and mixtures thereof; (iv) about 0.1-5% of a thickener stabilizer selected from the group consisting of cellulose gum, magnesium aluminum silicate and mixtures thereof; (v) about 1-30% of a stabilizing polishing agent selected from the group consisting of bentonite, titanium dioxide, silica, magnesium, oxide and mixtures thereof; and (vi) purified water; the paste component and gel component being combined immediately prior to use.

3 Claims, 9 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 4

BRIEF SUMMARY:

1 This invention relates to a dental preparation useful in the treatment of gum disease, to a method of storing and delivering such preparation to a use point and to an article for the storage and delivery of such preparation.

2 It has long been recognized that the combination of hydrogen peroxide solution with sodium bicarbonate and table salt has an excellent curative and preventive effect on gum disease caused by bacterial infection. Dr. Paul H. Keyes has advocated use of this combination to the dental profession and to the public at large based on his work of more than 25 years on the subject, which has shown that upon daily and diligent topical application of these materials, gum disease may be effectively controlled. On the basis of his recommendations, many dentists urge their patients to use the Keyes procedure (substantially as described e.g. in S. Elder: "An Alternative To Gum Surgery" Modern Maturity, Aug.-Sept. 1980 pp. 31-32).

3 Dr. Keyes advocates that a quantity of solid sodium bicarbonate be placed in one hand, and that the toothbrush held in the other hand, be dipped into a hydrogen peroxide -table salt solution and then transferred to the bicarbonate

and applied to the teeth and gums. Upon contact with the gums, the hydrogen peroxide is exposed to the enzyme catalase, which is always present in the buccal cavity, and is attached thereby resulting in the release of active oxygen. The combination of the active oxygen and the sodium bicarbonate together with table salt destroys the bacteria responsible for gum disease. Unfortunately, hydrogen peroxide and sodium bicarbonate may not be premixed, as they immediately react and are thereby rendered ineffective against gum disease. In addition, hydrogen peroxide is unstable and therefore difficult to store for prolonged periods of time. Finally, mere dipping of the toothbrush in a hydrogen peroxide solution does not insure delivery of a sufficient amount of hydrogen peroxide to the teeth and gums. These factors are responsible for the fact that use of the Keyes procedure is extremely awkward, inconvenient and messy. Another disadvantage stems from the fact that, the mixture of hydrogen peroxide and sodium bicarbonate has a very unpleasant taste. For these reasons, patients have shown extreme reluctance to follow this procedure, especially on a daily basis, as would be required for effective gum disease control. As a result, the benefits which the Keyes procedure affords have largely been left unrealized.

4 Accordingly, it is an object of this invention to eliminate the above disadvantages associated with use of the Keyes procedure by providing a dental preparation incorporating the active constituents of the Keyes procedure that has pleasant taste and is neat and convenient to use, and a method for using such preparation that permits contact between hydrogen peroxide and sodium bicarbonate only shortly before use and, therefore, assures maximum effectiveness against gum disease.

5 It is another object of the present invention to provide a dental preparation incorporating the active constituents of the Keyes method and a method for using such preparation that permits a sufficient, consistent and reproducible amount of hydrogen peroxide to be delivered to the use point.

6 It is yet another object of this invention to provide an article for the storage and delivery of this improved dental preparation which makes its use neat and convenient and which prevents contact between hydrogen peroxide and sodium bicarbonate prior to application.

DRAWING DESCRIPTION:

In accordance with the present invention, hydrogen or urea peroxide is dissolved in a nontoxic gel for use in combination with a separately stored but substantially simultaneously dispensed paste containing sodium bicarbonate, table (or another suitable) salt, and, preferably, additional cleansing, anticaries and polishing agents as well as an effective concentration of flavoring substances. Each of the gel and paste are loaded either into separate collapsible containers which are connected by means of a common orifice (as in FIG. 1), or which have substantially adjacent orifices (as in FIG. 2), or in separate compartments of a single container (as in FIGS. 3 or 4). Alternatively, the gel and paste may be loaded in separate compartments of a two-compartment pressurized container (as in FIG. 5) or a mechanically actuated pump, as in FIG. 6.

Upon substantially simultaneous squeezing of the containers, in much the same way as common toothpaste tubes (or upon actuating of the pressurized container or pump), controlled quantities of the gel and paste can be simultaneously released onto the toothbrush and immediately applied to the teeth and gums. Control of the peroxide, salt, and NaHCO.sub.3 quantities delivered may be thus effected by specification of the opening of the orifice and the active ingredient concentration in each tube (or pump compartment). As described above, when the brush is applied to teeth and gums, immediate mixing of the products takes place followed by the rapid evolution of active oxygen and carbon dioxide. At the same time, the effervescence accompanying release of active oxygen activates the flavor contained in the bicarbonate paste and produces a lasting highly refreshing taste in the mouth which is unlike any other flavor provided by existing toothpastes or gels.

Another advantage afforded by the present invention, as compared with the Keyes procedure, is that a greater and more consistent amount of peroxide is delivered to the use point.

Yet another advantage stems from the tendency of the present composition to cling to the gum tissues and thus provide them with the full benefit of substantially all of the composition applied to the gums.

Gelling agents suitable for use in preparation of the peroxide gel in accordance with this invention should be nontoxic and neutral to the peroxide to assure its stability. In addition, they should be preferably sensitive to external electrolytes, such as those contained in the sodium bicarbonate paste, in order to make peroxide immediately available to the oral tissues. A gelling agent suitable for use with the present invention is a copolymer of acrylic acid cross-linked with polyallyl sucrose, as described in U.S. Pat. No. 2,798,053 issued on July 2, 1957 and assigned to B. F. Goodrich Inc. Other gelling agents resulting in stable hydrogen (or urea) peroxide gels suitable for use in the present invention include those described in British Pat. No. 827,331, i.e, organic polymeric acid colloids including polyuronic acids, carboxypolymethylene compounds and polyester resins containing three carboxyl groups, such as partially hydrolized polyacrylates or polymethacrylates and copolymers thereof; and those described in U.S. Pat. No. 3,639,574 issued on Feb. 1, 1972 to Schmolka, i.e., polyoxyethylene polyoxypropylene block copolymers, which, according to Schmolka, may be used in the preparation of stable, firm hydrogen peroxide gels. Preferred are water-dispersible copolymers of acrylic acid cross-linked with about 0.75 to about 1.5% of polyallyl sucrose and neutralized with triethanolamine, NaOH or another alkalizing agent, as taught in U.S. Pat. No. 3,499,844.sup.1/ issued on Mar. 10, 1970 to Kibbel et al. For purposes of the present invention, Kibbel's acrylic copolymer may be preferably combined with an anionic or non-ionic surfactant, such as disclosed in U.S. Pat. No. 4,130,501.sup.2/ issued on Dec. 18, 1978 to Lutz et al. Such surfactants are not essential for the formation of a stable hydrogen peroxide gel in accordance with this invention, but may be added to facilitate distribution and rapid penetration of the active oxygen throughout the area to be treated. A particularly preferred gelling agent for the purposes of the present invention is that described by Kibbel, supra. This gelling agent may but does not have to be modified by the addition of a suitable amount of non-ionic cellulose gum such as hydroxyethyl- or hydroxypropyl-cellulose or hydroxypropyl-methyl-cellulose in order to improve the physical stability of the gel, especially when subjecting it to stress such as that resulting from squeezing of the collapsible tubes, or pumping action.

1/ The disclosures of these patents are incorporated herein by reference.

2/ The disclosures of these patents are incorporated herein by reference.

The most preferred gelling agents are marketed under the trademark CARBOPOL 941 and 1342 by Goodrich. Carbopol 941 does not need neutralization for gelling (and preferably is not neutralized in this invention) because it gels readily in the presence of hydrogen donors. Carbopol 941 has proved to have greater long term physical stability (also believed to be due to hydrogen bonding). Although Carbopol 1342 has just become available on the market and its composition and characteristics have not been fully disclosed, it is claimed by the manufacturer that this acrylic acid copolymer (even through it needs to be neutralized) displays satisfactory long term stability comparable to that of Carbopol 941.

Gels made from these agents do not need any cellulose additive as a stabilizer, because they are thixotropic (and also pseudoplastic).

Not only is Carbopol 941 the most preferred gelling agent for non-neutralized gels, it is also most preferred for neutralized gels along with Carbopol 934, 940 and 1342.

The hydrogen peroxide gel may then contain the following ingredients in the following amounts - H.sub.2 O.sub.2 : about 0.1-10.0% and preferably about 3.0-6.5%; Acrylic acid copolymer: about 0.05-5.0% and, preferably, about 1.0-3.0%; nonionic

cellulose gum (optional): about 0-2.0% and, preferably, about 0.3-1.5%; neutralizing agent (triethanolamine, diisopropanolamine, NaOH, KOH): an amount sufficient to raise the gel pH to about 3.0-6.0; NaOH is preferred. The balance is purified (distilled or deionized) water.

If a non-neutralized gelling agent is used, the aforementioned gel may contain about 2-80% and preferably about 20-60% by weight of a polyol selected from the group consisting of glycerin, sorbitol (70% solution) polypropylene glycol, propylene glycol, polyethylene glycol, ethoxylated or propoxylated lower (C.sub.2 -C.sub.5) fatty alcohols and mixtures thereof. The preferred polyol is glycerin. The amount of the water is decreased so that the total adds up to 100% by weight. The pH need not be controlled but falls between about 2 and 4.

The sodium bicarbonate paste contains sodium bicarbonate, sodium chloride (or another suitable salt although the salt may be omitted, if desired), purified (distilled or deionized) water, a thickener/stabilizer such as cellulose gum and or magnesium-aluminum silicate, as essential ingredients and, most preferably, it also contains a polishing/stabilizing agent, such as bentonite, silica, titanium dioxide, magnesium oxide or mixtures thereof (the first three and their mixtures are preferred). In order to disperse the "chalky" taste imparted mostly by the bicarbonate and enhance the taste and plasticity of the paste, a bodying agent is added, such as sorbitol, glycerin and/or a glycol. In addition, if the paste (in combination with the gel) is to displace toothpaste completely, additional cleansing agents, such as calcium sulfate, calcium phosphate, hydrated aluminum oxide, calcium carbonate, magnesium carbonate, and magnesium silicate or mixtures thereof can be added. A fluorine-containing compound is also preferably included for its anti-caries activity. Suitable fluorine-containing compounds are NaF, Na-monofluorophosphate, KF, potassium monofluorophosphate, sodium fluorosilicate, sodium fluorozirconate, etc. (with NaF being most preferred). Finally, a foaming agent such as sodium lauryl sulfate (most preferred), sodium N-lauroyl sarcosinate, sodium coconut monoglyceride sulfonate, sodium N-methyl-N-palmitoyl lauride or a nonionic surfactant such as a polysorbate (e.g., Tween 60 or 80 manufactured by ICI Americas, Wilmington, Delaware) or poloxamer or mixtures thereof, which also enhances the peroxide-bicarbonate-salt action, may be added. Flavoring agents, such as sodium saccharin, or other artificial sweeteners, peppermint or spearmint or other flavors are preferably added to further curb the unpleasant taste. Finally, methyl, butyl and/or propyl paraben, sodium benzoate, potassium sorbate or mixtures thereof are preferably added as preservatives, with methyl and propylparaben being most preferred. Use of a coloring agent is optional.

The constituents and quantities for the bicarbonate paste are as follows:

sodium bicarbonate: about 2-60% and preferably 20-40%;

salt: about 0-6%, preferably about 1-6% and most preferably about 2-4% of NaCl (preferred) or KCl, MgCl.sub.2, MgSO.sub.4, Na.sub.2 SO.sub.4 or K.sub.2 SO.sub.4 or mixtures thereof;

humectant: about 2-60% and preferably, 15-25% consisting of glycerin, sorbitol propylene glycol, polyethylene glycol, polypropylene glycol, ethoxylated or propoxylated lower fatty alcohols and mixtures thereof;

thickener-stabilizer: nonionic cellulose gum--about 0.1-5% and preferably 1.0-2.0%; or magnesium aluminum silicate or mixtures thereof in the same proportions;

stabilizer/polishing agent/cleanser: total about 1-30%, preferably about 1.5-20%; these preferably include one or more of: bentonite--about 0.5-7.5%; silica--about 0.1-8.0%; titanium dioxide--about 0.1-8.0%; and/or magnesium oxide--about 0.2-8.0%; preferably, about 1.5-5.0; 0.5-6.0; 0.5-3.0; and 0.5-3.0 percent, respectively.

fluorine-containing compound: sufficient to yield 200 to 3,000 ppm and preferably 1,000 to 2,000 ppm fluorine;

foaming agent: about 0.1-2.5%; preferably about 0.2-0.5%;

additional polishing agents: total about 1-30%, preferably about 5-20%;

flavoring agent(s): to taste, preferably 0.1-2%;

preservatives: about 0.05-0.5%.

The balance is purified water. A coloring agent may be added. The paste and the gel are preferably used in substantially equal proportions, by volume.

If urea peroxide is used in the gel, the bicarbonate paste composition does not change. The gel composition will be as follows:

urea peroxide: about 2-25%, preferably about 8-12%;

acrylic copolymer: about 0-3.5, preferably about 1-3%;

glycerin: balance.

The other polyols described above are reactive with the urea peroxide and should not be used.

The gel and paste combination may be simultaneously dispensed from separate collapsible tubes preferably made of plastic, or a plastic/metal laminate (to avoid reaction with H.sub.2 O.sub.2) and enhanced flavor retention), such as tubes 1 and 2 shown in FIG. 1. The tubes are fitted with a Y-shaped conduit 3 which provides them with a common orifice 6. Conduit 3 may also be made of plastic (preferably by injection molding) and is preferably detachably but snugly attached to mouths 4,5 of tubes 1,2 so that it may be removed for cleaning. For additional convenience and in order to ensure dispensation of substantially equal amounts of the gel and paste, the tubes themselves may be held together, e.g., by banding or creaming, along corresponding dorsal sides, shown in FIG. 1, or, preferably, along corresponding ventral sides (see, e.g., FIG. 3A).

Alternatively, the two tubes may be constructed to have a common (preferably flat) sidewall portion 26 as shown in FIG. 2. In the latter case, the Y-shaped conduit may be unnecessary, if the mouths 24,25 of tubes 21,22 are sufficiently close so that sufficient quantities of the gel and paste may be simultaneously dispensed directly on the toothbrush. Conventional toothpaste or medicament tubes may be thus used after one of their side walls and the corresponding portion of their head structure are permanently deformed (e.g. by application of pressure) to a substantially flat surface.

A third alternative packaging method involves loading each of the gel and paste into separate compartments of the same collapsible tube, joined by a common orifice, as shown in FIG. 3. Composite tube 31 has compartments 32, 33 separated by divider 34 which is firmly attached along substantially diametrically opposed portions 35, 36 of the sidewall 37, and corresponding portions 38,39 of head structure 40. Divider 34 may be glued or welded to sidewall 37 and head structure 40 of tube 31 during manufacture of the latter. Divider 34 is preferably provided with protruding portion 41, which extends into the mouth 42 of tube 31 until its edge is substantially flush with rim 43 of mouth 42. Thus, divider 34 forms with sidewall 37 two separate compartments 32,33 of substantially the same volume for storage of the gel and paste, respectively.

In another alternative packaging method, the two tubes are "concentric" as shown in FIG. 4A. Inner tube 401 lies within and parallel with outer tube 402.

The mouths of the tubes 401 and 402, designated as 405 and 404 in FIG. 4, abut at the same point. Tube 401 is fastened on to tube 402 at the mouth by protrusion 406 (shown in enlargement in FIG. 4B, which is a cross-section of the embodiment of FIG. 4A taken along 4B--4B). Protrusions 406 are inserted in a groove of mouth 404 of tube 402. The material contained in tube 402 can still pass through the available space between mouth 404 of outer tube 402 and mouth 405 of inner tube 401. Engagement of pins 406 in the groove secures the inner tube 401 on the other tube 402.

The closure 407 of the tube-within-a-tube (which can screw on the outer tube or simply be held by pressure) arrangement may but does not have to be equipped with an interior protrusion 408 to fit in the inner tube in order to prevent premature intermixing of the two components at the mouth of the tube. Because of the pseudoplastic quality of the gel and/or the memory of the plastic tube, however, such intermixing is not likely to occur. The tubes are filled from the bottom and are (subsequently) sealed together by conventional techniques.

Other alternative packaging arrangements are disclosed in FIGS. 5 and 6. Pressurized container 501 in FIG. 5 is provided with two compartments 502 and 503 and two spouts 504 and 505. The internal pressure of the compartments is maintained by pressurized nitrogen, at the bottom 506 of each compartment. Operation of the mechanical actuator 507 (by pressing downwards) actuates valves 508 and 509 which release the contents of the compartments through the spouts (channels) causing the upwardly slidable sealing disks 510 and 511 (guided by members 512, 513) to move up along the compartments (due to the nitrogen being under pressure). Similar (but conventional) pressurized containers are manufactured for example by American Can Company. A dual compartment container, as described above, would be a modification of the existing containers.

In an alternative pump embodiment depicted in FIGS. 6 and 7 a pressurized container 601 is provided with two compartments 602 and 603, and two spouts 604 and 605 for dispensing the gel and paste. Located within the tube 605 is a first piston 606 which is held in place by the upper surface of the contents within compartment 603 and a tubular extension 607 fitting within the lower portion of spout 605. A spring 608 is under compression and is held in position by the upper conical surface 609 of piston 606 and an inner shelf 601 of the spout 605. Lower pistons 611 and 612 are positioned within the lower portions of compartments 602 and 603 respectively so as to follow the dental material upwardly as it is being dispensed into the spouts 604 and 605 and eventually into nozzle 613. The upper part of container 601 has a reduced diameter to encircle the nozzle 613 and provide for a sliding engagement. Outer cap member 614 is threadedly engaged as at 615, with outer surface of nozzle 613 to effectively seal the container and prevent inadvertent dispensing of dental material as well as a pin 616 which fits snugly into open end of nozzle 613.

In operation, and with cap 614 removed, the user will depress a push button lever 617 (seen in FIG. 7) located outside the container 601. Lever 617 has substantially flat elongated member 618 which projects between spouts 604 and 605 and presses against wall 619 which bridges both spouts. Lever 617 is pivoted about pivot pin 620 affixed to inner wall of container 601. As lever 617 is depressed, member 618 will force spouts 604 and 605 downwardly and subsequently spring 608 as well as piston 606 will be lowered to phantom position (as seen in FIG. 6) causing dental material to flow upwardly within extension 607 and spout 605, mixing with material in spout 604 and through nozzle 613 to the bristles of a toothbrush. As the lever is released, the spring 608 will force nozzle 605 upwardly to its original position against conical portion 621 to container 601. The vacuum created will cause piston 606 to raise upwardly and concomitantly cause lower piston 612 to travel upwardly the distance of the expelled dental material. A spring clip 621 slideably engages inner surface of compartment 603 to allow piston to travel upwardly but be prevented from movement downwardly. Description of compartment 602 and spout 604 with its accompanying component parts operate in a like manner as described above.

The particular packaging arrangement used is not important. Those skilled in the art will be able to fashion several obvious modifications of the containers described herein by way of illustration.

Tubes, such as those suitable for use in accordance with the present invention are usually extruded around a cylindrical mandrel, cut into tube segments of suitable length, fitted with head structures and then filled from the bottom and pressed and/or welded closed, substantially as described in, e.g., U.S. Pat. No. 4,060,179 issued on Nov. 29, 1977 to McGhie, the disclosure of which is incorporated herein by reference.

In the case of the tube-within-a-tube embodiment of the present invention, the outer

tube is provided first but it is not closed at the end opposite to that of the closure. The inner tube (also open-ended at the corresponding end) is inserted and fastened to the mouth of the outer tube. The two tubes are then filled and sealed together. A similar tube-within-a-tube arrangement has been proposed and described in U.S. Pat. No. 1,566,218 of Leland and issued on Dec. 15, 1925, incorporated here by reference.

DETAILED DESCRIPTION:

1 The invention is further illustrated by the following specific examples which are designed merely to illustrate the present invention and not to limit its scope.

2 In these examples, a hydrogen peroxide gel containing 3-6.5% hydrogen peroxide by weight, useful for simultaneous administration with a sodium bicarbonate paste is prepared as follows:

3 EXAMPLE 1

Ingredients	
Hydrogen peroxide, 35% aqueous solution	14.3 parts
(5% H.sub.2 O.sub.2 in final gel)	
Purified water	84.45
Copolymer of acrylic acid crosslinked with	0.5
1% by weight of polyallyl sucrose having 5.8 allyl groups per molecule (CARBOPOL 934 made by B. F. Goodrich Chemical Co., Akron,Ohio)	
Hydroxyethyl cellulose	0.5
Triethanolamine	0.25

4 The gel is prepared by combining the hydrogen peroxide solution with the purified water, followed by the gradual addition of CARBOPOL 934. Upon thorough dispersion of the copolymer hydroxyethyl cellulose is slowly added and dissolved. Finally, triethanolamine is added, forming a clear, homogeneous, stable and viscous gel having a pH of 3.4.

5 EXAMPLE 2

Ingredients	
Hydrogen peroxide, 35% aq. solution (3.5% H.sub.2 O.sub.2 in final gel)	10.0 parts
Distilled or deionized water	88.9
Acrylic acid copolymer CARBOPOL 940 (Goodrich)	0.6
Hydroxyethylcellulose	0.5
Sodium hydroxide, 10% solution	q.s. pH 3.8-4.0

Preparation: same as that of Example 1.

6 EXAMPLE 3

Ingredients	
Hydrogen peroxide, 35% (3.5% H.sub.2 O.sub.2 in final gel)	10.0 parts
Distilled or deionized water	89.0
Acrylic acid copolymer - CARBOPOL 941 (Goodrich)	0.7
Hydroxypropylcellulose	0.3
Sodium hydroxide, 10% solution	q.s. pH 3.8-4.0

7 Preparation: same as that of Example 1.

8 EXAMPLE 4

Ingredients	
Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5 parts
Distilled or deionized water	86.65
Acrylic acid copolymer - CARBOPOL 934 (Goodrich)	0.75
Sodium laurylsulfate, dentifrice grade	0.50
Hydroxypropylcellulose	0.6
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.5

9 Preparation:

10 The hydrogen peroxide solution is combined with the distilled or deionized water. Sodium laurylsulfate is added under constant agitation and dissolved. Gradually, CARBOPOL 934 is added and dispersed. Hydroxypropylcellulose is added in increments and dissolved. When the mixture is homogeneous, sodium hydroxide is added slowly to the desired pH level and viscosity.

11 EXAMPLE 5

Ingredients	
Hydrogen peroxide, 35% (6.0% H.sub.2 O.sub.2	17.14 parts

in final gel)	
Distilled or deionized water	81.76
Acrylic acid copolymer - CARBOPOL 940 (Goodrich)	0.70
Hydroxyethylcellulose	0.40
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.0

12 Preparation: same as that of Example 1.

13 EXAMPLE 6

Ingredients	
Hydrogen peroxide, 35% (3.0% H.sub.2 O.sub.2 in final gel)	8.58 parts
Distilled or deionized water	89.22
Acrylic acid copolymer - CARBOPOL 934 (Goodrich)	0.70
Hydroxypropyl methylcellulose	0.65
Nonionic surfactant PLURONIC F 127 (BASF Corp., New Jersey)	0.85
Sodium hydroxide, 10% solution	q.s. pH 3.5-4.5

14 Preparation: same as that of Example 4.

15 EXAMPLE 7

16 The sodium bicarbonate paste is prepared as follows:

Ingredients	
Deionized water	31.94 parts
Sorbitol 70% solution, USP	20.0
Cellulose gum - CMC 7MF (Hercules)	1.44
Sodium saccharin	0.20
Magnesium aluminum silicate - VEEGUM F (made by R. T. Vanderbilt Co., Inc., Norwalk, Conn.)	1.17
Sodium bicarbonate, fine powder	40.00
Sodium chloride	4.00
Sodium lauryl sulfate - dentifrice grade	0.30
Peppermint/Spearmint Flavor	

	0.75
Methyl paraben, USP	0.15
Propyl paraben, USP	0.05

17 Procedure:

18 Glycerin and propylene glycol are combined in a first container with agitation. Cellulose gum is added and dispersed thoroughly throughout the mixture. Saccharin, methylparaben and propylparaben are added to the required amount of purified water in a separate container and heated to dissolve. VEEGUM is added and the mixture is agitated until uniform. The contents of the first container are slowly added to the second container and the final mixture is agitated thoroughly until uniform. Flavoring agent, sodium lauryl sulfate and coloring (if desired) are added and the paste is agitated at moderate speed until uniform. Entrapped air is removed by degassing in a vacuum vessel. Further homogeneity may be obtained by milling, if necessary.

19 EXAMPLE 8

Ingredients	
Deionized water	33.43 part
Glycerin	10.00
Propylene glycol	10.0
Cellulose gum - CMC 7MF (Hercules)	1.45
Sodium saccharin	0.20
Magnesium aluminum silicate - VEEGUM F	1.17
Sodium bicarbonate, fine powder	25.00
Dicalcium phosphate dihydrate	13.50
Dicalcium phosphate, anhydrous	1.50
Sodium chloride	2.50
Sodium lauryl sulfate, dentifrice grade	0.30
Methylparaben, USP	0.15
Propylparaben, USP	0.05
Peppermint/Spearmint Flavor	0.75
FD & C Blue No. 1, 0.1% solution	q.s.
DS & C Yellow No. 6, 0.1% solution	q.s.

20 EXAMPLE 9

21 Paste containing fluoride:

Ingredients	
Deionized water	33.51

Sorbitol, 70% solution	20.00
Sodium saccharin	0.20
Cellulose gum CMC 7MF (Hercules)	1.54
Magnesium aluminum silicate - VEEGUM F	1.17
Sodium fluoride	0.33
Methyl paraben, USP	0.15
Propyl paraben, USP	0.05
Calcium sulfate	10.00
Sodium bicarbonate	25.00
Sodium chloride	2.00
Hydrated aluminum oxide	5.00
Peppermint/Spearmint Flavor	0.75
Sodium lauryl sulfate	0.30

22 Procedure: Same as that of Example 8.

23 EXAMPLE 10

24 Peroxide Gels

Composition 10-A	
Hydrogen peroxide, 35% aqueous solution (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	86.6
Acrylic acid copolymer - Carbopol 934 (Goodrich)	1.5
Sodium lauryl sulfate, dentifrice grade	0.1
Hydroxypropyl cellulose	0.3
Sodium hydroxide, 10% solution	q.s. pH 3.0-4.5
Composition 10-B	
Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	88.0
Acrylic acid copolymer (Carbopol 934, 940, 941, or 1342)	1.5
Sodium hydroxide, 10% solution	q.s. pH 3.0-4.5
Composition 10-C	
Hydrogen peroxide, 35% (4.0% H.sub.2 O.sub.2 in final gel)	11.5
Distilled water	46.0
Glycerin, anhydrous	40.0
Acrylic acid copolymer - Carbopol 941	2.5

25 Methods of preparation

26 Composition 10-A: same as listed in Example 4

27 Composition 10-B: same as in Example 4 except that sod. lauryl sulfate and

hydroxypropyl cellulose were omitted. The composition including Carbopol 1342 has not been actually made.

28 Composition 10-C: The glycerin and water were combined and heated to 50.degree.-60.degree. C. Very slowly, Carbopol 941 was added under constant agitation.

29 When a clear gel had formed and no undissolved lumps remained, the gel was cooled to 25.degree. C. and the hydrogen peroxide was added. Agitation was maintained until the mixture became homogeneous. The gel was de-aerated in a vacuum vessel.

30 EXAMPLE 11

31 Sodium bicarbonate Paste

Composition 11-A	
Glycerin	25.0
Cellulose gum CMC 7MF (Hercules)	1.54
Deionized water	32.71
Magnesium aluminum silicate Veegum (R. T. Vanderbilt)	1.10
Sodium saccharin	0.60
Sodium chloride	2.0
Methyl paraben	0.15
Propyl paraben	0.05
(Sodium hydroxide solution 10%, q.s. pH 8.0-8.5, may be added, if necessary for pH adjustment)	
Sodium fluoride	0.22
Bentonite	4.0
Titanium dioxide	2.0
Silica	4.0
Sodium bicarbonate	25.0
Flavor (spearmint)	1.0
Sodium lauryl sulfate	0.3
Color (FDC Blue No. 1) q.s.	

32 Method of preparation

33 The cellulose gum was added to the glycerin and dispersed thoroughly.

34 In a separate vessel, the parabens, sodium saccharin and sodium chloride were dissolved in water at 60.degree.-70.degree. C. To the clear solution was added the Veegum and the mixture was agitated until uniform. The pH of this solution was determined to be 8.0-8.5 (and adjusted, if necessary).

35 The gum dispersion was added to the Veegum solution and agitated until uniform.

36 To the blend were added the powders, bentonite, TiO.sub.2, silica, NaHCO.sub.3, and NaF, under vigorous agitation.

37 To the paste were added flavor, sodium lauryl sulfate and color.

38 The finished paste is milled and degassed in a vacuum vessel.

39 EXAMPLE 13

40 Urea peroxide gel

Composition 13-A		
Urea peroxide (35% H.sub.2 O.sub.2 equivalent)	10.0	parts by weight
Glycerin, anhydrous	90.0	

41 Method: Urea peroxide is slowly added under agitation to the anhydrous glycerin until a clear gel is formed which has s suitable consistency for filling into collapsible tubes.

Composition 13-B	
Urea peroxide	10.0
Acrylic acid copolymers - Carbopol 941	1.5
Glycerin, anhydrous	88.5

42 The method is the same as that for 13-A except the urea peroxide and Carbopol 941 are both added to the glycerin solution.

43 Although the present invention has been described with reference to preferred embodiments, those of ordinary skill in the art will readily appreciate that many additions, deletions, modifications and substitutions are possible within the spirit of the present invention and the scope of the following claims.

CLAIMS:

What is claimed is:

1. A composition useful in combatting gum disease comprising:

(a) a gel component comprising (i) about 0.1-10% by weight of hydrogen peroxide; (ii) about 0.05-5.0% by weight of a water-dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) about zero to about 2.0% by weight of a nonionic cellulose stabilizer; (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in an amount sufficient to raise the gel pH to about 3-6.0; and (v) purified water;

(b) a paste component comprising: (i) about 2-60% sodium bicarbonate; (ii) about 0-6% of a salt selected from the group consisting of NaCl, KCl, MgCl.sub.2, MgSO.sub.4, Na.sub.2 SO.sub.4 and K.sub.2 SO.sub.4 ; (iii) about 2-60% of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol, propylene glycol, polypropylene glycol, an ethoxylated lower fatty alcohol, a propoxylated lower fatty alcohol and mixtures thereof; (iv) about 0.1-5% of a thickener stabilizer selected from the group consisting of cellulose gum, magnesium aluminum silicate and mixtures thereof; (v) about 1-30% of a stabilizing polishing agent selected from the group consisting of bentonite, titanium dioxide, silica, magnesium oxide and mixtures thereof; and (vi) purified water; said paste component and gel component being combined immediately prior to use.

2. The composition of claim 1, wherein said gel component comprises about 3.0-6.5% hydrogen peroxide; about 1-3% of said copolymer; and about 0.3-1.5% of said neutralizing agent.

3. The composition of claim 2, wherein said paste component comprises about 20-40% of said sodium bicarbonate; about 2-4% of said salt; about 15-255 of said humectant; about 1.0-2.0% of said stabilizer; and about 1.5-20% of said stabilizing polishing agent.

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L4: Entry 1 of 1 File: USPT Jan 12, 1999

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TITLE: Dental bleaching compositions with high concentrations of hydrogen peroxide

DATE-ISSUED: January 12, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Jensen; Steven D.	Midvale	UT		
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

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PRIOR-ART-DISCLOSED:

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ART-UNIT: 171

PRIMARY-EXAMINER: Anthony; Joseph D.

ABSTRACT:

Dental bleaching compositions that include a high concentration of bleaching agent and a bleaching agent stabilizer that maintains the potency of the bleaching agent over time. The dental bleaching compositions of the present invention may be one-part, pre-mixed compositions that do not require mixing at the time of treating a patient's teeth but which remain stable over time. The bleaching agent may consist of hydrogen peroxide, either in aqueous form or complexed with urea (carbamide peroxide) or sodium perborate. The bleaching agent stabilizer includes an impurity scavenger that binds or ties up impurities, such as errant or residual metal ions, that can cause decomposition of the bleaching agent. The bleaching agent stabilizer may include a carboxylic acid chelator or a tin salt. The bleaching composition may include a thickening agent to achieve a selected viscosity and a neutralizing agent to adjust the pH and a carrier to help provide selected consistency and potency. The dental bleaching compositions may be adapted to be loaded into and delivered from a syringe.

34 Claims, 0 Drawing figures
Exemplary Claim Number: 1

BRIEF SUMMARY:

1 BACKGROUND OF THE INVENTION

2 1. The Field of the Invention

3 The present invention relates to dental bleaching compositions and methods for treating tooth surfaces. More particularly, the present invention is directed to a stable one-component viscous/gelled dental bleaching composition that has a high concentration of bleaching agent. The dental bleaching compositions of the present invention can optionally include a radiant-energy and/or heat-energy absorbing substance which can absorb these forms of energy and cause the bleaching agent to more quickly bleach the tooth surfaces.

4 2. The Relevant Technology

5 The use of certain foods and tobacco, the process of aging, diseases, trauma, medications, some congenital conditions, and environmental effects can cause teeth to become discolored. Because white or whitened teeth are usually considered to be aesthetically superior to stained or discolored teeth, there has been a heightened level of interest of late in developing compositions and methods for bleaching teeth.

6 A tooth is comprised of an inner dentin layer and an outer hard enamel layer that is slightly porous. The natural color of the tooth is opaque to translucent white or off-white.

7 Some dentrifices, like toothpastes, gels, and powders, contain active oxygen or hydrogen peroxide liberating bleaching agents. Such bleaching agents include peroxides, percarbonates and perborates of the alkali and alkaline earth metals or complex compounds containing hydrogen peroxide. Also, peroxide salts of the alkali or alkaline earth metals are known to be useful in whitening teeth.

8 The most commonly used dental bleaching agent is carbamide peroxide (CO(NH.sub.2).sub.2.H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians for several decades as an oral antiseptic. Tooth bleaching was an observed side effect of extended contact time. Over-the-counter compositions of 10% carbamide peroxide are available as "GLY-OXIDE.RTM." by Marion Laboratories and "PROXIGEL.RTM." by Reed and Carnrick. An extended-contact application of bleaching gel held in a dental tray is available as "OPALESCENCE.RTM." by Ultradent. Other bleaching agents such as peroxyacetic acid (CH.sub.3 C.dbd.OO--OH) and sodium perborate, are also known in the medical, dental and cosmetic arts.

9 Patients who have desired to have their teeth whitened have typically done so by applying a bleaching composition to the teeth by means of the dental tray for repeated treatments, or they had to submit to conventional in-office bleaching techniques that required from 4 to 10 visits to the dental office before clinically significant results were achieved. Less effective teeth whitening was also done by the use of toothpastes or polishes that were applied by brushing. Clinically significant results are quantifiable such as by measuring gray scale, L*, and as to yellowness or blueness, b*, in the CIE.RTM. system of color measurement or by equivalent methods.

10 Bleaching compositions have been manufactured in one-part and two-part systems. A one-part system consists of a compound in which the active bleachant is dispersed into inert components to form an emulsion or gel. One-part systems can also further consist of mixtures in which stabilizers are used to prevent

premature decomposition of the peroxide in the bleaching composition. The advantage of a one-part system is ease of use and convenience. The main disadvantage is that prior art one-part viscous/gelled bleaching compositions generally contain relatively low concentrations of peroxide. High concentrations in pre-mixed gells have not been stable. Thus, current one-part systems have a low potency and are slow to react. Most one-part systems in the past have included active peroxide in a range of up to about 3.5% by weight. Due to the relatively low concentration of active bleaching agent in one-part systems, about 10 applications on average are necessary for effective bleaching.

11 In a two-part system, aqueous hydrogen peroxide is mixed with other components to achieve a preferred higher viscosity. These components are mixed just prior to bleaching due to the incompatibility of the other components with hydrogen peroxide. The main advantage of a two-part system is that it allows for much higher concentrations of active peroxide that cannot exist stably as a one-part system for incidental off-the-shelf use. This results in faster bleaching of the patient's teeth due to the higher peroxide concentration. Faster bleaching is desirable, especially where patient compliance with longer bleaching regimens is problematic, or if only one or a few teeth need individual bleaching.

12 Another example of a two-part system is microencapsulation of the bleaching agent and a stabilizer. The microcapsules would separate the bleaching agent from the carrier and other materials and would rupture only upon physical shear caused by a tooth brush. The dental bleaching effect of the microencapsulation system is only visible after prolonged use due to its low peroxide concentration or low activation rate.

13 Although positive results using the foregoing techniques have been reported, the effectiveness of the techniques depends upon such factors as type and intensity of the stain, bleaching agent contact time on the teeth, the amount of available active bleachant in the bleaching agent, and the persistence of the individual in applying the treatment until the desired result is accomplished.

14 Notwithstanding the foregoing advantages, there remain some important disadvantages to current one-part and two-part systems. A disadvantage to the two-part system is that the bleaching composition must be mixed on-site in the operatory immediately before application to the patient's tooth. Mixing requires additional time by the dental professional, which lowers efficiency and represents an extra preparatory procedure. Mixing in proper amounts is also important in order to yield consistent results.

15 Another disadvantage where high peroxide concentrations are used is that bleaching compositions that must be mixed on-site in the operatory subject the dental professional to the possibility of burns due to mixing splatter. Additionally, high concentrations of hydrogen peroxide are strong oxidizers.

16 Another disadvantage with two-part bleaching compositions is that, once mixed, the bleaching compositions must be used soon, since they are unstable and tend to decompose through the release of oxygen from the peroxide moieties. Often, the constituents of the bleaching compositions themselves accelerate decomposition rates. While such accelerants are useful in promoting faster bleaching, they yield a composition having a very short lifespan. Because known accelerants are chemical in nature, they cannot be added until bleaching is to commence. Otherwise the premature release of active oxygen will quickly decrease the potency of the bleaching composition. Moreover some accelerant(s) or peroxide indicators are unstable in that they themselves are consumed by the peroxide. The tendency of prior art accelerants or indicators to be themselves consumed has the effect of reducing the concentration of both the peroxide and the accelerant over a short period of time, thus reducing the effectiveness of each.

17 From the foregoing, it will be appreciated that what is needed in the art are stable, one-part, pre-mixed viscous/gelled bleaching compositions and methods for treating tooth surfaces that allow for greatly increased bleaching rates compared to existing one-part systems.

18 Additionally, it would be a significant advancement in the art to provide stable, one-part, pre-mixed viscous/gelled dental bleaching compositions for treating tooth surfaces that included means for accelerating the release of active oxygen from the bleaching agent when needed but which do not cause premature decomposition of the active dental bleaching agent or destruction of the bleaching agent activator.

19 It would still be a further advancement in the art to provide stable, one-part, pre-mixed viscous/gelled dental bleaching compositions that included higher concentrations of bleaching agent compared to existing one-part compositions that are made at the time of manufacture.

20 Such stable, one-part, pre-mixed dental bleaching compositions and methods for bleaching tooth surfaces are disclosed and claimed herein.

21 SUMMARY AND OBJECTS OF THE INVENTION

22 The present invention comprises stable, one-part, pre-mixed dental bleaching compositions made with a bleaching agent and a radiant-energy absorbing constituent that acts as a bleaching agent activator. The dental bleaching compositions of the present invention are one-part, pre-mixed compositions a with sufficient shelf life to allow for storage in a dental professional's operatory for use when needed. Preferred bleaching agents include peroxides such as hydrogen peroxide and carbamide peroxide (which is a complex between urea and hydrogen peroxide). Preferred bleaching agent activators include radiant-energy absorbing substances, preferably substantially conjugated hydrocarbons such as aromatic rings or conjugated chains, that are stable in the presence of the bleaching agent in varying concentrations and that will not cause premature decomposition of the bleaching agent before the composition has been irradiated with radiant energy.

23 A thickening agent can be used to give the dental bleaching composition a desired consistency, thickness, and viscosity. Preferred thickening agents include PEMULEN.RTM., a proprietary compound from B.F. Goodrich, or a compositional or chemical equivalent thereof.

24 An important advantage of the bleaching compositions of the present invention are that they are stable over time. A major cause of premature degradation of the bleaching agent is the existence of errant or residual metal ions that can act as bleaching agent catalysts. Hence, it is possible to create stable bleaching compositions even at high concentrations (greater than 20% by weight) by avoiding, removing, or trapping errant or residual metal ions.

25 Scavenging of errant or residual metal ions can be accomplished by means of a bleaching agent stabilizer. The bleaching agent stabilizer comprises edetate disodium, EDTA, oxine EDTA, calcium disodium EDTA, adipic acid, succinic acid, citric acid and their respective salts,, tin nitrates, tin phosphates, their combinations, and the like.

26 Activation of the dental bleaching composition of the present invention is accomplished with a bleaching agent activator that is preferably a radiant-energy or heat-energy absorbing substance. Examples of such substances include radiant-energy absorbing, substantially conjugated hydrocarbons such as aromatic hydrocarbons, multiple double-bond hydrocarbon chains, chain-aromatic mixtures, reacted combinations thereof, and equivalents. Specific examples include caroteneoids such as bixin, lycoxanthin, lycophil, canthaxanthin, capsanthin, cryptoxanthin, isomers of carotene, and lycopene. Other specific examples include aromatics such as coronene, fluoranthene, naphtho[2,3-a] pyrene, trans-4,4'-diphenylstilbene, 9,10-diphenylanthracene, 5,12-bis

(phenyethynyl) napthacene, 9,10-bis (phenylethynyl) anthracene, and perylene. The foregoing compounds may optionally include one or more carboxyl groups. The only limitations are (1) that the radiant-energy absorbing substance does not cause substantial peroxide decomposition over time, and (2) that the radiant-energy absorbing substance be substantially peroxide resistant in the presence of the bleaching agent over time. Preferred bleaching agent activators include 9,10-bis (phenylethynyl) anthracene, perylene, and isomers of carotene and carboxyl-substituted variations thereof.

27 The bleaching compositions preferably include an inert or non-problematic carrier. The carrier may include, but is not limited to water, polypropylene glycol, polyethylene glycol, sorbitol, propylene glycol, glycerol, steryl alcohol, large molecular weight polyols, mixtures of the foregoing, and equivalents.

28 Because the bleaching compositions of the present invention are both stable in a one-part, pre-mixed system and include the radiant-energy absorbing substance, the bleaching process is greatly simplified. The dental bleaching compositions may advantageously be either pre-loaded or loaded manually into and dispensed from a syringe onto the patient's teeth. The dental professional simply places a desired quantity of the dental bleaching composition on the patient's teeth and then triggers accelerated bleaching by either irradiating the bleaching composition with radiant energy, such as visible and/or UV light, or by applying e.g. conductive heat energy to the composition before, during, or after application to the teeth. Depending on the desired rate of bleaching and patient sensitivity to bleaching agents, a bleaching composition having the optimum amount of bleaching agent can be selected before bleaching commences or can be determined by noting the results of the first bleaching treatment.

29 In view of the foregoing, it is an object of the present invention to provide stable, one-part, pre-mixed bleaching compositions and methods for treating tooth surfaces that allow for greatly increased bleaching rates compared to existing one-part systems.

30 It is a further object and feature of the present invention to provide stable, one-part, pre-mixed viscous/gelled dental bleaching compositions for treating tooth surfaces that include means for accelerating the release of active oxygen from the bleaching agent when needed but which does not cause premature decomposition of the active dental bleaching agent or destruction of the bleaching agent activator.

31 In addition, it is an object of the present invention to provide stable, one-part, pre-mixed viscous/gelled dental bleaching compositions that include higher concentrations of bleaching agent compared to existing one-part compositions. In connection with this object of the present invention, it is an added object of the present invention to provide a high potency, active oxygen liberating bleaching composition that does not require mixing immediately before use, thus avoiding the danger of splatter burns on the clinician or the patient.

32 These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 The one-part, pre-mixed viscous/gelled dental bleaching compositions of the present invention are comprised of several components that, working in concert, provide a stable and effective viscous/gelled one-part, pre-mixed dental bleaching composition. The inventive bleaching compositions are stable over

time but can be caused to accelerate bleaching by means of radiant or heat energy. The components include a bleaching agent, a thickening agent or gelling agent, a neutralizing agent, a carrier, a bleaching agent stabilizer, and a bleaching agent activator. Each component contributes to the dental bleaching composition in different ways.

3 A. Bleaching Agents.

4 Preferred bleaching agents include hydrogen peroxide and hydrogen peroxide-containing complexes, such as carbamide peroxide (NH.sub.2).sub.2 CO--H.sub.2 O.sub.2. Peroxides can provide a ready source of active oxygen in effective concentrations.

5 Hydrogen peroxide is the preferred bleaching agent in some cases, especially where it is desired to include a relatively high concentration of bleaching agent concentrations. Because of the nature of hydrogen peroxide, it is only available as an aqueous solution. Aqueous available hydrogen peroxide solutions from 3% to 90% by weight hydrogen peroxide are commercially available.

6 On the other hand, carbamide peroxide can provide a nonaqueous form of available hydrogen peroxide. Carbamide peroxide in its pure form is a crystalline substance consisting of a molecule of urea complexed with a single molecule of hydrogen peroxide. Carbamide peroxide is generally more stable than aqueous hydrogen peroxide and is often preferred for that reason. However, because of the existence of the urea molecule, pure crystalline urea peroxide contains only about 36% available hydrogen peroxide. This means that the upper limit of available peroxide for bleaching when only using carbamide peroxide is lower than 36% when significant quantities of other components such as water, proplyene glycol, or glycerol and the like are included in the bleaching composition.

7 The type and amount of hydrogen peroxide to be used will depend on the desired peroxide concentration in the final dental bleaching composition. In general, it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to manufacture a bleaching composition having high concentrations of bleaching agent. Lower concentrated hydrogen peroxide solutions and/or carbamide peroxide and/or sodium perborate are generally used when it is desired to manufacture a bleaching composition having lower concentrations of bleaching agent. Carbamide peroxide solutions and hydrogen peroxide solutions can be mixed together in varying concentrations to yield bleaching compositions having a wide spectrum of bleaching agent concentrations. Additionally, sodium perborate can be used alone or it can be mixed with each or both of hydrogen peroxide and carbamide peroxide.

8 Because hydrogen peroxide is generally less stable with increasing pH, many hydrogen peroxide solutions include acidifying agents such as mineral acids in order to render a more stable hydrogen peroxide solution. However, upon mixing such solutions with the other constituents to yield the dental composition of the present invention, it will generally be desired to adjust the pH to an acceptable pH range in order to protect the patient's teeth and surrounding tissues. The concept of pH adjustment will be discussed herein below.

9 B. Thickening Agents.

10 Thickening agents or gelling agents assist to increase viscosity, to facilitate ease of placement, and to assure the composition stays in place during treatment. Thickening agents preferably have the quality of being substantially inert in the presence of, and not readily decomposed by, the bleaching agent. It has been found that thickening agents that are substantially hydrophilic but have a relatively small lipophilic moiety, are preferred in the present invention. For example, a preferred thickening agent is an emulsifier comprising a high molecular weight polyacrylic acid polymer or copolymer.

11 As an example of a preferred thickening agent, we have found that PEMULEN.RTM.

or a compositional or chemical equivalent thereof possesses the qualities required for the inventive composition. A more preferred thickening agent is PEMULEN.RTM. TR-1NF. PEMULEN.RTM. is a propriety formula that includes a significant quantity of a polyacrylic copolymer that has a slightly hydrophobic end and a strongly hydrophilic end.

12 In addition to PEMULEN.RTM. or a compositional or chemical equivalent thereof, we have found that silicates may be used; however, the composition loses its gell like qualities that are preferred during application.

13 C. Neutralizing Agents.

14 In light of the acidity of some hydrogen peroxide solutions and polyacrylic acid thickeners such as PEMULEN or a compositional or chemical equivalent thereof, it is usually desired to use a neutralizing agent to adjust the pH to within an acceptable pH range. Raising the pH causes some thickeners to become more viscous. In addition, bleaching compositions that are too acidic can etch the patient's teeth and cause irritation to surrounding dental tissues. In most cases, the pH will be in a range from about 2 to about 9, more preferably in a range from about 3 to about 7, and most preferably from about 4 to about 6. Preferred neutralizing agents include alkali hydroxides, such as sodium hydroxide and potassium hydroxide, amines such as diisopropanol amine and triethanol amine, ammonium hydroxide, and the like. The most preferred neutralizing agent is sodium hydroxide, 50 percent in distilled or deionized water.

15 D. Carriers.

16 The carrier is used to complement the other dental bleaching composition components and effect good dispersion and stability of the resulting compositions. By adjusting the amount of carrier, the bleaching agent concentration can be adjusted to a selected level. The use of a carrier or carrier combinations aligned with a thickening agent allows for achievement of a selected bleaching agent concentration and a selected consistency. Water, or water in combination with other components including other carriers is sometimes used. Other carriers include polyols, such as polypropylene glycol and polyethylene glycol, sorbitol, propylene glycol, glycerol, steryl alcohol, ethylene glycol, large molecular weight polyols and the like and mixtures of the above. Although ethylene glycol could work as a carrier, it is not used because it is toxic.

17 E. Bleaching Agent Stabilizers.

18 The bleaching agent stabilizers act as impurity scavengers that bind with errant or residual metal ions and other impurity elements that might cause decomposition of the bleaching agent. The stabilizer also must not itself be a source of bleaching agent instability. Where an excess of stabilizer is in solution such that all impurities have been bound up by the stabilizer, the excess stabilizer must itself be inert to the bleaching agent. At least two classes of bleaching agent stabilizers are part of the present invention. One class comprises carboxylic acid chelators, such as edetate disodium, EDTA, oxine EDTA, calcium disodium EDTA, adipic acid, succinic acid, citric acid, and the like and mixtures thereof, their respective salts or derivatives. Another class of bleaching agent stabilizers consists of tin-containing salts, such as tin nitrates, tin phosphates, and the like.

19 F. Bleaching Agent Activators.

20 Several bleaching agent activators are disclosed in the present invention such as radiant or thermal energy absorbable bleaching agent activators. The preferred qualities of bleaching agent activators include inertness to the bleaching agent and the ability to absorb energy and heat up, thus activating the bleaching agent.

21 Inert particles that act as a heat sink may also be used. These particles may absorb radiant or conducted thermal energy in such a way so as to not substantially chemically react with the peroxide during application. Such particles may include metals coated with inert films or metal-filled plastic resins.

22 It has been found that radiant energy absorbable, substantially conjugated hydrocarbons are the preferred bleaching agent activators since they appear to be significantly stable in the presence of peroxides. In other words, they themselves resist oxidation or bleaching in the presence of the bleaching agent.

23 Preferred bleaching agent activators are defined as substantially conjugated hydrocarbons such as multiple benzene structures, conjugated hydrocarbon chains, and combinations thereof that absorb portions of the electromagnetic spectrum and that have simple hydrogen, hydroxyl, or carboxylic groups attached to the structures and that act as energy-absorbing substances.

24 The preferred multiple benzene structures can be as simple as naptha-based structures or anthracene-based structures. Useful substantially conjugated hydrocarbons that are benzene structures include 9,10-bis(phenylethynyl)-anthracene, perylene, naphtho[2,3-a]pyrene, trans-4,4'-diphenylstilbene, 9,10-diphenylanthracene, 5,12-bis(phenyethynyl)-napthacene, coronene, fluoranthene, and equivalents.

25 The known substantially conjugated bond hydrocarbon chains include caroteneoids, such as bixin, lycoxanthin, lycophil, canthaxanthin, capsanthin, cryptoxanthin, isomers of carotene, and lycopene. Of the known substantially conjugated hydrocarbons, 9,10-bis (phenylethynyl)-anthracene, perylene, and isomers of carotene are preferred. Of the known substantially conjugated hydrocarbons, carboxyl-substituted hydrocarbons are also preferred.

26 Less preferred aromatic compositions such as 7-diethylamino 4-methyl coumarin, henna, and alizarin are less stable compared to the above-defined substantially conjugated hydrocarbons. Henna, a red dye known for at least 4,000 years, is a double-ketonated naphtha hydroxide. Alizarin, a red dye, is a double-ketonated anthracene meta double hydroxide. Although 7-diethylamino 4-methyl coumarin, henna, and alizarin are less preferred, to the extent that one were to use these substances within a stable, one-part, pre-mixed bleaching composition, such a composition would certainly be within the scope of the present invention.

27 Other substantially conjugated hydrocarbon structures that resist oxidation by peroxides are within the skill of the routineer in the art to find during routine experimentation after consultation with the present invention disclosure or by practicing the invention.

28 The bleaching agent activators in the dental bleaching composition of the present invention will preferably not only efficiently absorb radiant energy but also preferably will not significantly contribute to bleaching agent decomposition while the composition sits on the shelf. In this way, the inventive bleaching composition will have substantially the same shelf life as a bleaching composition that does not include the bleaching agent activator when stored at an appropriate temperature, e.g. 4.degree. C. In addition to on-the-shelf inertness, it is also preferable that upon application of radiant energy, the bleaching agent activator itself does not substantially react with the oxidizer. The effect of a bleaching agent activator that resists oxidation during patient treatment is an increase in available activator relative to the remaining unreacted bleaching agent.

29 As radiant energy is applied to the dental bleaching composition, the bleaching agent activator begins to heat up and to accelerate the release of active oxygen from the bleaching agent.

30 G. General Properties.

31 To make the dental bleaching composition of the present invention a viable off-the-shelf product for dental professionals, hydrogen peroxide decomposition must be minimized during storage. Because hydrogen peroxide decomposition is accelerated by increasing the temperatures, it is appropriate to store the inventive dental bleaching composition within an appropriate temperature range. e.g. about 4.degree. C. A preferred shelf life is at least about one month, where the amount of available bleaching agent is at least about 95% of the original concentration. For about two months, it is preferable for there to remain at least about 90% of the original available bleaching agent. For about three months, it is preferable for there to remain at least about 80% of the original available bleaching agent.

32 Obviously, it will generally always be preferable to have more stable systems in which most, if not all, of the bleaching agent remains active over the length of the shelf life. It has been observed that dental bleaching compositions of the present invention remained substantially undecomposed for about three months. For example, samples of the inventive dental bleaching composition were stored refrigerated for 92 days and there remained about 99% of the original available hydrogen peroxide. Samples of the inventive dental bleaching composition were stored refrigerated for 127 days and there remained above 98% of the original available hydrogen peroxide. Additionally, samples of the inventive dental bleaching composition were stored unrefrigerated for 92 days and there remained about 95% of the original available hydrogen peroxide. Because periodic testing of available hydrogen peroxide revealed slow decomposition of the bleaching agent after about three months, it is within the contemplation of the present invention that if refrigerated, uncontaminated, and light-shielded, the inventive dental bleaching composition will contain about 50%, preferably about 90%, and most preferably about 95% of the original available hydrogen peroxide for about one year.

33 Stability of a dental bleaching composition with about 35% available hydrogen peroxide, wherein the dental bleaching agent maintains at least about 85% of its original strength about one month after manufacture, is understood to be a composition that would contain about 30% available hydrogen peroxide.

34 The dental bleaching compositions of the present invention can be made such that they include from about 20% to about 90% available hydrogen peroxide; from about 0.05% to about 5% thickening agent; from about 0% to about 10% neutralizing agent; from about 5% to about 80% carrier; from about 0.01% to about 5% stabilizer; and from about 0.001% to about 3% bleaching agent activator.

35 More preferred dental bleaching compositions of the present invention can be made such that they include from about 25% to about 80% available hydrogen peroxide; from about 0.5% to about 4% thickening agent; from about 0.5% to about 5% neutralizing agent; from about 10% to about 75% carrier; from about 0.1% to about 3% stabilizer; and from about 0.02% to about 2% bleaching agent activator.

36 Most preferred dental bleaching compositions of the present invention can be made such that they include from about 30% to about 60% available hydrogen peroxide; from about 1% to about 3% thickening agent; from about 0.6% to about 3% neutralizing agent; from about 15% to about 65% carrier; from about 0.5% to about 2% stabilizer; and from about 0.05% to about 1% bleaching agent activator.

37 H. Methods of Use.

38 In light of the foregoing inventive features of the dental compositions of the present invention, the method for bleaching teeth is performed in the dental operatory under ordinary conditions. The dental professional applies a layer of the inventive dental bleaching composition on the labial surfaces of as many of

the teeth as are desired to be bleached.

39 Thereafter, rapid bleaching is carried out by irradiating the teeth with radiant energy, such as visible and/or UV radiant energy, to accelerate decomposition of the bleaching agent. The radiant energy excites the dental bleaching activator, which causes the molecular bonds within the activator to vibrate vigorously and heat up the composition. The heated composition causes the accelerated release of free radical oxygen from the dental bleaching agent. The rate of heating can be controlled by the amount of light that is used.

40 The dental bleaching compositions may advantageously be loaded into and dispensed from a syringe onto the patient's teeth.

41 I. Examples of the Preferred Embodiments.

42 In order to more fully teach the present invention, the following examples are presented. The examples are intended to be illustrative only and are certainly not intended to imply that other embodiments not specified are not within the scope of the present invention. Bleaching compositions were prepared according to the present invention and included the components and amounts set forth as Examples 1-28, which are set forth below in Table 1.

43 In order to illustrate one exemplary manner of mixing together the components, attention is turned to Example 4, in which 254 g of propylene glycol was placed in a container and mixed with 12 g of PEMULEN.RTM. TR-1NF until homogenous. Next, stabilizers comprising 8 g each of edetate disodium and citric acid were mixed with water and added as stabilizers to the glycol-PEMULEN mixture to scavenge errant or residual metal ions. Thereafter, 4 g of beta carotene was added as the bleaching agent activator. Following addition of the bleaching agent activator, 705 g of 50% aqueous hydrogen peroxide was added. To the mixture was added 9 g of sodium hydroxide, 50% in water, and the resulting mixture was stirred until homogeneous. The other examples were mixed together in similar fashion, although the concentrations and identities of the components were altered in order to form the compositions as achieved.

44 Table 1 represents 28 exemplary compositions that were prepared according to the present invention and identified as Examples 1-28. In each sample, the bleaching agent was added in the form of aqueous hydrogen peroxide; therefore the number under the heading "H.sub.2 O.sub.2 " represents the net amount of hydrogen peroxide in the composition. Thus, the balance of the aqueous hydrogen peroxide was water. The thickener was PEMULEN.RTM. TR-1NF unless otherwise noted. The neutralizing agent was sodium hydroxide in 50% water. Other components are noted at the foot of Table 1.

TABLE 1

Example	Active H.sub.2 O.sub.2	Water	Thickener	NaOH	Carrier	Stabilizer	Activator	Total
1	30.25	30.25	1.2	0.9	36.4.sup.1	1.0.sup.2	--	100.0
2	30.5	30.5	1.5	0.8	36.7.sup.3	--	--	100.0
3	30.5	30.5	1.2	0.9	36.9.sup.4	--	--	100.0

4	35.25	35.25	1.2	0.9	25.4.sup.1	1.6.sup.5	0.4.sup.6	100.0
5	35.25	35.25	1.2	0.9	27.4.sup.3	--	--	100.0
6	35.25	35.25	1.2	0.9	27.4.sup.4	--	--	100.0
7	35.25	35.25	1.2	0.9	27.4.sup.6	--	--	100.0
8	35.25	35.25	1.2	0.9	27.3.sup.3	1.0.sup.2	--	100.0
9	35.25	35.25	1.2	0.9	27.2.sup.3	0.2.sup.2	--	100.0
10	35.25	35.25	1.2	0.9	26.4.sup.1	1.0.sup.2	--	100.0
11	35.25	35.25	1.2	0.9	26.4.sup.4	1.0.sup.2	--	100.0
12	35.25	35.25	1.2	0.9	26.0.sup.1	1.0	0.4.sup.7	100.0
13	35.25	35.25	1.2	0.9	26.0.sup.1	1.4.sup.8	--	100.0
14	35.25	35.25	1.2	0.9	25.9.sup.1	1.5.sup.9	--	100.0
15	35.25	35.25	1.2	0.9	25.5.sup.1	1.5.sup.9	0.4.sup.10	100.0
16	35.25	35.25	1.2	0.9	25.8.sup.1	1.5.sup.9	0.1.sup.10	100.0
17	35.25	35.25	1.2	0.9	25.5.sup.1	1.8.sup.11	0.1.sup.10	100.0
18	35.25	35.25	1.2	0.9	25.7.sup.1	1.6.sup.12	0.1.sup.10	100.0
19	35.25	35.25	1.2	0.9	25.7.sup.1	1.8.sup.13	0.1.sup.10	100.0
20	35.25	35.25	1.2	0.9	25.0.sup.1	2.3.sup.14	0.1.sup.10	100.0
21	35.25	35.25	1.2	0.5	26.1.sup.1	1.8.sup.13	0.1.sup.10	100.0
22	35.25	35.25	1.2	0.9	25.3.sup.1	2.0.sup.15	0.1.sup.10	100.0
23	35.25	35.25	1.2	0.5	25.7.sup.1	2.0.sup.15		

							0.1.sup.10	
								100.0
24	35.25	35.25	1.2	0.9	25.5.sup.1			
						1.8.sup.16		
							0.1.sup.10	
								100.0
25	35.25	35.25	1.2	1.3	25.1.sup.1			
						1.8.sup.13		
							0.1.sup.10	
								100.0
26	35.25	35.25	1.2	0.9	25.1.sup.1			
						2.2.sup.17		
							0.1.sup.10	
								100.0
27	40.25	40.25	1.2	0.9	17.4.sup.3			
						--	--	100.0
28	40.25	40.25	1.2	0.9	17.4.sup.4			
						--	--	100.0

.sup.1 Propylene glycol; .sup.2 Adipic acid:succinic acid 1:1; .sup.3 Distilled water; .sup.4 Glycerine; .sup.5 Edetate disodium:citric acid 1:1; .sup.6 Polyethylene glycol 300; .sup.7 Bis(phenylethynyl)anthracene; .sup.8 Edetate disodium:adipic acid:succinic acid 0.8:1:1; .sup.9 Edetate disodium:adipic acid:succinic acid 1:1:1; .sup.10 Perylene; .sup.11 Edetate disodium:adipic acid:succinic acid 1:6:1:1; .sup.12 Edetate disodium:citric acid 1:1; .sup.13 Edetate disodium; .sup.14 Edetate disodium:adipic acid:succinic acid:citric acid 1:6:1:1:1:1; .sup.15 Edetate disodium:EDTA 1:1; .sup.16 Citric acid:EDTA 0.8:1; .sup.17 Edetat disodium:citric acid 1.75:1.

45 Of the foregoing, Example Nos. 2, 3, 5-7, 27 and 28 were prepared without using any stabilizer and without any bleaching agent activator. Upon measuring the concentration of active hydrogen peroxide over time, it was found that the hydrogen peroxide in these examples was not as stable as those formed with a stabilizer. The rate of decomposition was observed to increase as the concentration of hydrogen peroxide increased. This increased decomposition rate demonstrates the importance of the bleaching agent stabilizer in the event that a stable, one-part, pre-mixed bleaching composition is desired, particularly at higher concentrations of peroxide. These stabilizer-less compositions were also slow to react when irradiated with radiant energy and/or UV light from a standard dental curing light since they included no bleaching agent activator. Hence, in those cases where accelerated bleaching is desired, as opposed to slower but more steady bleaching, it is important to include the bleaching agent activator.

46 Of the foregoing examples set forth in Table 1, Example Nos. 1, 8-11, and 13-14 were made without any bleaching agent activator but did include a stabilizer, or a combination of stabilizers, according to the present invention. Upon measuring the concentration of active hydrogen peroxide over time it was found that the concentration of hydrogen peroxide in these examples remained above 90% of the original concentration after 28 days of storage. As in Example Nos. 2, 3, 5-9, 27 and 28, these compositions were slow to become activated when irradiated with visible and/or UV light using a commercial dental curing light. However, upon irradiating the compositions with heat energy using a heat lamp that emitted in the infrared range, accelerated decomposition of bleaching compositions within about 1 minute was observed.

47 Of the foregoing examples set forth in Table 1, Example Nos. 4, 12 and 15-26 were made to contain both a stabilizer and a bleaching agent activator according to the present invention. Upon measuring the concentration of active hydrogen peroxide over time it was found that the concentration of hydrogen peroxide in these examples remained above about 90% of the original concentration after 28 days of storage. Upon measuring the concentration of activator over time it was found that the concentration of the bleaching agent

activator color remained virtually unchanged after 28 days of storage at an appropriate temperature, e.g. 4.degree. C. Upon irradiating these compositions with visible and/or UV light using a commercial dental curing light, the compositions became activated. Because the concentration of activator remained stable over time, the slight drop in apparent stability of the hydrogen peroxide compared to compositions in which no activator was used was apparently due to the fact that the compositions were not prepared or stored in total darkness.

48 Although the use of a heat lamp caused the bleaching compositions to become activated, it is not particularly feasible to place a heat lamp near or inside a patient's mouth. Doing so might cause discomfort or injury. On the other hand, the use of visible and/or UV emitting lamps caused little if any discomfort since the heat that was generated was limited to within the bleaching composition as a result of the radiant-energy absorbing substance activator, and even that heat was mild compared to the heat generated by a heat lamp.

49 In order to more fully teach the invention, the following hypothetical examples are presented. While the compositions of the following examples were not actually physically mixed together, they were derived or extrapolated from actual mix designs and are based on the results determined by observing the behaviors of actual mix designs.

50 Examples 29-41 are made according to the mixing sequence set forth above for Example 4, except that the identities and concentrations of the various components are altered as set forth in Table 2 below.

TABLE 2

Example	Active H.sub.2 O.sub.2	Water	Thickener	NaOH	Carrier	Stabilizer	Activator	Total
29	3.5	3.5	1.2	0.8	90.0.sup.1	1.0.sup.2	--	100.0
30	10	10	1.2	0.8	76.9.sup.1	1.0.sup.2	0.1.sup.10	100.0
31	20	20	1.2	0.8	57.0.sup.1	1.0.sup.2	--	100.0
32	20	20	1.2	0.8	56.9	1.0.sup.2	0.1.sup.10	100.0
33	25	25	1.2	0.8	47.0	1.0.sup.2	--	100.0
34	25	25	1.2	0.8	46.9	1.0.sup.2	0.1.sup.10	100.0
35	40.25	40.25	1.2	0.9	16.0.sup.1	1.3.sup.2	0.1.sup.10	100.0
36	50.0	33.4	1.2	0.9	11.6.sup.1	2.8.sup.2		

							0.1.sup.10	100.0
37	55.0	29.9	1.2	1.2	9.5.sup.1	3.1	0.1.sup.10	100.0
38	60.0	26.4	1.2	1.3	7.6.sup.1	3.4	0.1.sup.10	100.0
39	70.0	19.4	1.2	1.6	19.6.sup.1	3.9	0.1.sup.10	100.0
40	80.0	12.4	1.2	1.8	--	4.5	0.1.sup.10	100.0
41	90.0	1.9	1.2	1.8	--	5.0	0.1.sup.10	100.0

.sup.1 Propylene glycol; .sup.2 Adipic acid:succinic acid 1:1; .sup.10 Perylene.

51 Of the foregoing, Example Nos. 29, 31 and 33 are made without any bleaching agent activator but do include a stabilizer or a combination of stabilizers according to the present invention.

52 Of the foregoing compositions, Example Nos. 30, 32,and 34-41 include both a stabilizer and a bleaching agent activator according to the present invention. The hydrogen peroxide concentration in these examples remains at a level of at least about 80% of the original concentration after 28 days of storage, while the bleaching agent activator color remains virtually unchanged after 28 days of storage. When irradiated, each of the compositions in these examples is activated.

53 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrated and not restrictive. The scope of the invention is, therefore, indicated by the appended claims and their combination in whole or in part rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A stable, one-part dental bleaching composition for bleaching a person's teeth comprising a bleaching agent, a bleaching agent stabilizer, and a thickening agent, wherein the dental bleaching agent maintains at least 60% of its original strength about three months after manufacture of the bleaching composition and wherein the bleaching agent provides available hydrogen peroxide when initially applied to the person's teeth in a concentration of at least about 20% by weight of the bleaching composition.

2. A stable, one-part dental bleaching composition as defined in claim 1, wherein the hydrogen peroxide maintains at least about 95% of its original strength about one month after manufacture of the bleaching composition.

3. A stable, one-part dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises aqueous hydrogen peroxide.

4. A stable, one-part dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide.

5. A stable, one-part dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises sodium perborate.

6. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent provides available hydrogen peroxide in a range from about 20% to about 90% by weight of the dental bleaching composition when initially applied to the person's teeth.

7. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent provides available hydrogen peroxide in a range from about 25% to about 80% by weight of the dental bleaching composition when initially applied to the person's teeth.

8. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent provides available hydrogen peroxide in a range from about 30% to about 60% by weight of the dental bleaching composition when initially applied to the person's teeth.

9. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent stabilizer comprises a metal ion scavenger.

10. A stable, one-part dental bleaching composition as defined in claim 1, wherein the dental bleaching agent maintains at least about 80% of its original strength about three months after manufacture of the bleaching composition.

11. A stable, one-part dental bleaching composition as defined in claim 1, wherein the dental bleaching agent maintains at least about 90% of its original strength about three months after manufacture of the bleaching composition.

12. A stable, one-part dental bleaching composition as defined in claim 1, wherein the composition maintains a flowable, gel-like consistency.

13. A stable, one-part dental bleaching composition as defined in claim 1, wherein the thickening agent comprises a polyacrylic acid polymer or copolymer that has a lipophilic portion and a hydrophilic portion.

14. A stable, one-part dental bleaching composition as defined in claim 1, further including a radiant energy absorbing constituent that acts as a bleaching agent activator.

15. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent stabilizer comprises a tin salt.

16. A stable, one-part dental bleaching composition as defined in claim 15, wherein the tin salt is selected from the group consisting of tin nitrates, tin phosphates, and mixtures of the foregoing.

17. A stable, one-part dental bleaching composition as defined in claim 1, further including a carrier.

18. A stable, one-part dental bleaching composition as defined in claim 17, wherein the carrier is selected from the group consisting of water, polypropylene glycol, polyethylene glycol, sorbitol, propylene glycol, glycerol, sterol alcohol, large molecular weight polyols, and mixtures of the foregoing.

19. A stable, one-part dental bleaching composition as defined in claim 1, further including a neutralizing agent.

20. A stable, one-part dental bleaching composition as defined in claim 19, wherein the neutralizing agent is included such that the dental bleaching composition has a pH in a range from about 2 to about 9.

21. A stable, one-part dental bleaching composition as defined in claim 19, wherein the neutralizing agent is included such that the dental bleaching

composition has a pH in a range from about 3 to about 7.

22. A stable, one-part dental bleaching composition as defined in claim 19, wherein the neutralizing agent is included such that the dental bleaching composition has a pH in a range from about 4 to about 6.

23. A stable, one-part dental bleaching composition as defined in claim 1, wherein the bleaching agent stabilizer comprises a carboxylic acid chelator.

24. A stable, one-part dental bleaching composition as defined in claim 23, wherein the carboxylic acid chelator is selected from the group consisting of edetate disodium, EDTA, oxine EDTA, calcium disodium EDTA, adipic acid, succinic acid, citric acid, salts of the foregoing, and mixtures of the foregoing.

25. A stable, one-part dental bleaching composition for bleaching a person's teeth comprising a bleaching agent, a thickening agent, a carrier, and a bleaching agent stabilizer selected from the group consisting of carboxylic acid chelators and tin salts, wherein the dental bleaching agent maintains at least 60% of its original strength about three months after manufacture of the bleaching composition and wherein the bleaching agent provides available hydrogen peroxide when initially applied to the person's teeth in a concentration of at least about 20% by weight of the bleaching composition.

26. A stable, one-part dental bleaching composition as defined in claim 25, wherein the hydrogen peroxide maintains at least about 95% of its original strength about one month after manufacture of the bleaching composition.

27. A stable, one-part dental bleaching composition as defined in claim 25, wherein the bleaching agent is sold premixed with the thickening agent, the carrier, and the bleaching agent stabilizer.

28. A stable, one-part dental bleaching composition as defined in claim 25, wherein the dental bleaching agent is selected from the group consisting of aqueous hydrogen peroxide, carbamide peroxide, sodium perborate, and mixtures thereof.

29. A stable, one-part dental bleaching composition as defined in claim 25, further including a radiant energy absorbing constituent that acts as a bleaching agent activator.

30. A stable, one-part dental bleaching composition for bleaching a person's teeth comprising a bleaching agent, a thickening agent, and a bleaching agent stabilizer, wherein the dental bleaching agent maintains at least 60% of its original strength about three months after manufacture of the bleaching composition and wherein the bleaching agent provides available hydrogen peroxide when initially applied to the person's teeth in a concentration of at least about 30% by weight of the bleaching composition.

31. A stable, one-part dental bleaching composition for bleaching a patient's teeth as defined in claim 30, wherein the hydrogen peroxide maintains at least about 95% of its original strength about one month after manufacture of the bleaching composition.

32. A stable, one-part dental bleaching composition as defined in claim 30, wherein the bleaching agent is sold premixed with the thickening agent, a carrier, and the bleaching agent stabilizer.

33. A one-part dental bleaching composition as defined in claim 30, wherein the dental bleaching agent is selected from the group consisting of aqueous hydrogen peroxide, carbamide peroxide, sodium perborate, and mixtures thereof.

34. A dental bleaching composition as defined in claim 30, wherein the

stabilizing agent is selected from the group consisting of edetate disodium, EDTA, oxine EDTA, calcium disodium EDTA, adipic acid, succinic acid, citric acid, salts of the foregoing, tin nitrates, tin phosphates, and mixtures of the foregoing.

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L5: Entry 1 of 2 File: USPT Aug 10, 1993

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TITLE: Sustained release method for treating teeth surfaces

DATE-ISSUED: August 10, 1993

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

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Search Selected Search ALL

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ART-UNIT: 333

PRIMARY-EXAMINER: Wilson; John J.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

5 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Prior Art

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam,

and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (3) expectorate any excess bleaching solution, (4) change the bleaching solution every 1 to 2.5 hours, and (5) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patient's. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them, gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth

discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high

viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B.F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental composition will be maintained over a greater period of time in a high salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range form about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed dropwise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention, gravity is not

sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patient's will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient's suspected of being breixers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional

bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agent within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase is effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs than with conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be

purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

37 The Carbopol 934P was obtained from B.F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced in a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that

the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The

scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by U.S. Letters Patent is:

1. A method for bleaching a patient's teeth comprising:

(a) obtaining a dental tray configured to cover a patient's teeth surfaces to be.bleached and configured to hold a quantity of sustained release dental bleaching composition;

(b) placing a quantity of sustained release dental bleaching composition within the dental tray said sustained release dental bleaching composition comprising:

a quantity of sustained release dental bleaching agent capable of bleaching vital tooth surfaces in contact with said sustained release dental bleaching agent; and

a matrix material into which the sustained release dental bleaching agent is dispersed, said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the sustained release dental bleaching composition;

(c) positioning the dental tray over the patient's teeth surfaces such that a portion of the sustained release dental bleaching agent is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth surfaces, said sustained release dental bleaching agent remaining active during a substantial time while the dental tray is positioned over the patient's teeth surfaces; and

(e) removing the dental tray from the patient's teeth.

2. A method for bleaching a patient's teeth as defined in claim 1, wherein the step of obtaining a dental tray further comprises obtaining a dental tray constructed with reservoirs for holding dental bleaching agent such that when the dental tray is positioned over the patient's teeth surfaces, the dental bleaching agent within the reservoirs is in contact with the patient's teeth surfaces to be bleached.

3. A method for bleaching a patient's teeth as defined in claim 1, further comprising the step of repeating steps (b) through (e).

4. A method for bleaching a patient's teeth as defined in claim 1, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 5 hours and wherein the sustained release dental bleaching agent remains active while the dental tray is positioned over the patient's teeth surfaces.

5. A method for bleaching a patient's teeth as defined in claim 1, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 8 hours and wherein the sustained release dental bleaching agent remains active while the dental tray is positioned over the patient's teeth surfaces.

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L5: Entry 2 of 2 File: USPT Mar 24, 1992

US-PAT-NO: 5098303
DOCUMENT-IDENTIFIER: US 5098303 A

TITLE: Method for bleaching teeth

DATE-ISSUED: March 24, 1992

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	Salt Lake City	UT			02

APPL-NO: 07/ 553168 [PALM]
DATE FILED: July 13, 1990

PARENT-CASE:
RELATED APPLICATION This application is a continuation-in-part of copending patent application Ser. No. 07/497,934, filed Mar. 22, 1990, in the name of Dan E. Fischer and entitled "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES," which is incorporated herein by specific reference.

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US-CL-ISSUED: 433/215
US-CL-CURRENT: 433/215

FIELD-OF-SEARCH: 433/215, 433/216, 433/217, 424/49

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

Search Selected | Search ALL

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ART-UNIT: 333

PRIMARY-EXAMINER: Wilson; John J.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

15 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to improved dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity dental compositions, such as tooth bleaching compositions, having significantly improved effectiveness and sustained release activity. The dental compositions may advantageously be used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Prior Art

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (3) expectorate any excess bleaching solution, (4) change the bleaching solution every 1 to 2.5 hours, and (5) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been recommended and prescribed by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended usage. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that either the bleaching agent must be frequently replaced during the day or the treatment extend for several weeks or months. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Since current home-use bleaching agents must be frequently replenished, the user necessarily ingests large volumes of the bleaching agent. In many cases, ingestion of the bleaching agent causes sore throats. Some researchers have

even suggested that long term repeated ingestion of large quantities of carbamide peroxide may be carcinogenic. Therefore, patient ingestion of dental bleaching compositions should be minimized.

11 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patient's. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

12 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

13 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

14 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

15 It would be another significant advancement in the art to provide dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

16 It would be an additional advancement in the art to provide dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

17 Such dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

18 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

19 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

20 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

21 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a saturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

22 The sustained release bleaching agents within the scope of the present

invention have such a high viscosity that positive pressure is needed to dispense them, gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

23 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

24 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

25 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

26 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

27 Recent experimental tests have compared one dental bleaching composition within the scope of the present invention with some commercially available dental bleaching compositions. All tested bleaching compositions had the same concentration of active ingredient (10% carbamide peroxide). The tests only examined bleaching effectiveness and did not consider increased effectiveness resulting from sustained release properties. The experimental results indicate that the present bleaching composition provides significantly greater effectiveness than the other tested bleaching compositions, irrespective of its sustained release properties. It is, therefore, an object of the present invention to provide highly effective dental bleaching compositions.

28 An additional object of the present invention is to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

29 Another important object of the present invention is to provide sustained release dental composition for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

30 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's

teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

31 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

32 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

FIG. 5 is a graph illustrating the results of Example 10.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the trade name "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. Some commercially available dental bleaching compositions contain low concentrations of carbopol. Importantly, it has been found that by preparing saturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to

about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of nonaqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, Carbopol 940 appears to dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 Another important advantage of the concentrated carboxypolymethylene compositions within the scope of the present invention is that on contact with saliva, the composition becomes initially firmer. As a result, a seal around the periphery of the dental tray is formed where the composition is in contact with saliva which keeps the remainder of the composition in contact with the teeth surfaces entrapped and "sealed" therein. The firmer material at the tray periphery also fills the minor discrepancies of the tray-to-tooth fit.

11 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental composition will be maintained over a greater period of time in a high salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene, relatively speaking, but still higher than typical concentrations, so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

12 The concentrated carboxypolymethylene composition also has a tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition not only keeps the composition within the reservoirs, but also retains the tray against the patient's teeth, thereby permitting softer, thinner, and more flexible tray materials to be used. It has been found that if too much carboxypolymethylene is used, the tackiness can decrease and the composition encumbers complete tray insertion.

13 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine enables the large quantities of carboxypolymethylene to be dispersed easier in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 40% to about 60% by weight.

14 In addition to functioning as a humectant, the glycerine also provides some flavor sweetening enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycols or other polyols.

15 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range form about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

16 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used; the use concentrated sodium hydroxide (50% NaOH) is one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

17 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

18 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed dropwise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention, gravity is not sufficient.

19 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

20 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor and control hoe many doses the patient has received and used.

21 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the

sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

22 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a syringe applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

23 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.035 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patient's will find 0.035 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient's suspected of being bruxers or hard biters may require a 0.06 inch tray material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

24 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

25 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

26 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

27 To achieve most rapid results, it is recommended to use sustained release bleaching agent within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase is effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs than with conventional trays without reservoirs.

28 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed

that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

29 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

30 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

31 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

32 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

33 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

34 If patient instructions are followed, more predictable results are obtained in days rather than weeks. Also, less total volume of bleaching agent is used (from 1/10 to 1/20 the volume of conventional peroxide solutions). As a result, less bleaching agent is swallowed by the patient.

35 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 2 to 4 three hour treatments, or 1 or 2 night-time treatments. One typical sustained release fluoride composition within the scope of the present invention contains 0.5% sodium fluoride in a high viscosity gel.

36 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

37 EXAMPLE 1

38 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight %
Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

39 The Carbopol 934P was obtained from B.F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

40 The foregoing procedure produced in a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

41 EXAMPLE 2

42 A sustained release dental bleaching composition within the scope of the present invention was made according to the procedure of Example 1, except that the ingredients were combined in the following amounts:

Ingredient	Weight	Weight %
Carbamide peroxide	1150	10
Water	2030	18
Glycerine	6660	59
Carbopol 934P	830	7
Sodium hydroxide	650	6

43 The foregoing procedure resulted in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.6%. The composition possessed a high viscosity and excellent sustained release teeth bleaching activity.

44 EXAMPLE 3

45 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent

Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

46 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

47 EXAMPLE 4

48 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

49 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

50 EXAMPLE 5

51 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

52 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

53 EXAMPLE 6

54 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

55 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

56 EXAMPLE 7

57 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

58 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

59 EXAMPLE 8

60 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5

Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

61 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

62 EXAMPLE 9

63 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight		Weight Percent
Sodium fluoride	52	gm	1.1%
Water	1000	gm	21.5%
Glycerine	2980	gm	64.1%
Carbopol 934P	380	gm	8.2%
Sodium hydroxide (50%)	238	gm	5.1%

64 The foregoing ingredients are mixed according to the procedure of example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

65 EXAMPLE 10

66 In this example, the in vitro brightening effect of two commercially available bleaching agents was measured and compared with the dental bleaching composition prepared according to the procedure of Example 1. Thirty-six (36) extracted anterior and premolar teeth without caries or restorations were randomly divided into four (4) groups and mounted. A thermoplastic splint was made for each group. In addition to the dental bleaching agent of Example 1, Denta-Lite (manufactured by Challenge Products, Osage Beach, MO) and Proxigel (manufactured by Reed P Carnrick, Piscataway, (N.J.) were tested. All of bleaching agents contained 10% carbamide peroxide as the active ingredient. Groups 1-3 were treated with the bleaching agents and group 4 was used as a control and bathed in sterile distilled water.

67 Bleaching agent was placed into a splint and replaced every 3 hours during the day and after 8 hours at night. The treatment continued for a period of 2 weeks averaging a minimum of 18 hours of bleaching per day. All teeth and splints were brushed and rinsed with water before replacing bleaching agents.

68 Measurements were taken using a Pentax photo spot meter, measuring brightness changes occurring at intervals of 24 hours, 72 hours, 7 days, and 14 days. The photo spot meter was equipped with an analog meter and the ability to read in 0.1 value variations. The meter was attached to a measuring apparatus which reflected two light sources at a 60 degree deflection angle toward the crown of the tooth being measured. A rheostat controlled the light sources to allow a

constant emittance during each measurement. The data were analyzed using a 2-way ANOVA and Duncan's multiple range test.

69 Photographs were taken before, at 72 hours, and at 14 days following bleaching. A 35 mm single reflex camera with a macro lens and a 2.times. diopter was used for all photography.

70 The results of this Example are reported in Table 1 and illustrated graphically in FIG. 5. They indicate that the dental bleaching composition within the scope of the present invention is over 50% more effective than the two commercially available dental bleaching agents having the same concentration of active ingredient. In fact, the bleaching agent of Example 1 provided greater whitening in just 3 days of treatment than the other bleaching agents did after two weeks of treatment.

71 It is important to recognize that the results of this Example to not address the impact of saliva on the effectiveness of the dental bleaching agents. The sustained release characteristics of the dental bleaching agent within the scope of the present invention were not addressed by this Example. Therefore, the effectiveness of the present invention can be expected to be even greater than the prior art bleaching agents when the sustained release activity is considered.

TABLE 1

Bleaching Effect of 10% Carbamide Peroxide
Value Changes: Means and standard deviations

Bleaching Agent	No.	24 Hrs.	72 Hrs.	7 Days	14 Days
Water	9	0	0	0	0
Example 1	9	.34 (.06)	.56 (.08)	.60 (.09)	.67 (.13)
Denta-Lite	9	.22 (.08)	.35 (.11)	.38 (.10)	.48 (.13)
Proxigel	9	.22 (.07)	.33 (.12)	.34 (.11)	.40 (.10)

72 Although much of the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other dental compositions, whether sustained release or not, may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the such dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

73 In some cases, the dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it

would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

74 From the foregoing, it will be appreciated the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

75 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

76 It will be further appreciated that the present invention provides dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

77 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

78 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A method for bleaching a patient's teeth comprising:

(a) obtaining a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition;

(c) positioning the dental tray over the patient's teeth surfaces such that a portion of the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth surfaces; and

(e) removing the dental tray from the patient's teeth.

2. A method for bleaching a patient's teeth as defined in claim 1, wherein the

step of obtaining a dental tray further comprises obtaining a dental tray constructed with reservoirs for holding additional dental bleaching composition such that when the dental tray is positioned over the patient's teeth surfaces, the additional dental bleaching composition within the reservoirs is in contact with the patient's teeth surfaces to be bleached.

3. A method for bleaching a patient's teeth as defined in claim 1, further comprising the step of repeating steps (b) through (e).

4. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a matrix material comprising carboxypolymethylene in the range from about 4.5% to about 10% by weight of the dental bleaching composition.

5. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a matrix material comprising carboxypolymethylene in the range from about 6% to about 8% by weight of the dental bleaching composition.

6. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a matrix material comprising carboxypolymethylene in the range from about 15% to about 35% by weight of the total quantity of water in the total dental bleaching composition.

7. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a matrix material comprising carboxypolymethylene in the range from about 20% to about 30% by weight of the total quantity of water in the total dental bleaching composition.

8. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a carbamide peroxide as the dental bleaching agent in the range from about 3% to about 20% by weight of the dental bleaching composition.

9. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray includes a carbamide peroxide as the dental bleaching agent in the range from about 4% to about 15% by weight of the dental bleaching composition.

10. A method for bleaching a patient's teeth as defined in claim 1, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 3 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

11. A method for bleaching a patient's teeth as defined in claim 1, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 5 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

12. A method for bleaching a patient's teeth as defined in claim 1, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 8 hours and wherein the dental bleaching composition remains active while the dental tray is positioned over the patient's teeth surfaces.

13. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray is sufficiently tacky to retain the dental tray positioned against the patient's teeth surfaces.

14. A method for bleaching a patient's teeth as defined in claim 1, wherein the quantity of dental bleaching composition placed within the dental tray becomes

firmer upon contact with saliva.

15. A method for bleaching a patient's teeth as defined in claim 1, wherein during the positioning step, a portion of the dental bleaching composition extends to the edge of the dental tray and forms a seal upon contact with saliva.

WEST

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L6: Entry 2 of 2 File: USPT Dec 27, 1994

US-PAT-NO: 5376006
DOCUMENT-IDENTIFIER: US 5376006 A

TITLE: Dental bleaching compositions and methods for bleaching teeth surfaces

DATE-ISSUED: December 27, 1994

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	Jordan	UT			02

DISCLAIMER DATE: 20090325

APPL-NO: 07/ 951713 [PALM]
DATE FILED: September 24, 1992

PARENT-CASE:
RELATED APPLICATION This application is a continuation of U.S. patent application Ser. No. 07/497,934, filed Mar. 22, 1990, now abandoned.

INT-CL: [05] A61C 5/00

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US-CL-CURRENT: 433/215; 252/186.27, 252/186.28, 252/186.29, 424/53, 424/616, 433/216

FIELD-OF-SEARCH: 252/186.27, 252/186.28, 252/186.29, 106/35, 433/215, 433/216, 424/53, 424/616

PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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Deposition of Dr. William Walter Klusemeier, Jr. with Exhibits.
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Deposition of Dan Parker with Exhibits.
Declaration of Paula Rains.
Declaration of Dr. Phil S. Sanders.
Deposition of Dr. Phil S. Sanders with Exhibits.
Declaration of Dr. Jerry Wagner.
Deposition of Dr. Jerry Wagner.

ART-UNIT: 223

PRIMARY-EXAMINER: Stoll; Robert L.

ASSISTANT-EXAMINER: Anthony; Joseph D.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

32 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Prior Art

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved

carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (3) expectorate any excess bleaching solution, (4) change the bleaching solution every 1 to 2.5 hours, and (5) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patient's. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate

patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them, gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional

bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time

consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental composition will be maintained over a greater period of time in a high salivating patient. However, in some cases it may be desirable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the to period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range form about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed

drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention, gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patient's will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient's suspected of being breixers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agent within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase is effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs than with conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

37 The Carbopol 934P was obtained from B. F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced in a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	

	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained

release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A method for bleaching a patient's teeth comprising the steps of:

(a) obtaining a dental tray configured to cover a patient's tooth surfaces to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, such that said matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that said matrix material is sufficiently tacky to retain and hold the dental tray positioned over the patient's teeth for a period greater than about 2 hours without any significant mechanical pressure from the dental tray;

(c) positioning the dental tray over the patient's teeth such that at least a portion of the dental bleaching composition is in contact with the patient's tooth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth for a period of time greater than about 2 hours;

(e) removing the dental tray from the patient's teeth.

2. A method for bleaching a patient's teeth comprising the steps of:

(a) obtaining a dental tray configured to cover a patient's teeth to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, and said matrix material including a quantity of water having a weight

percent of the total dental bleaching composition in a range from about 10% to about 60%, such that the matrix material has sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that the matrix material is sufficiently sticky to remain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray.

(c) positioning a dental tray over the patient's teeth surfaces such that a portion of the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth for a period of time greater than about 2 hours;

(e) removing the dental tray from the patient's teeth.

3. A method for bleaching a patient's teeth comprising the steps of:

(a) obtaining a dental tray configured to cover a patient's teeth to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including carboxypolymethylene and water in quantities such that the matrix material

(i) maintains sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces; and

(ii) remains sufficiently tacky in order to retain and hold said dental tray in place over the patient's teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray;

(c) positioning the dental tray over the patient's teeth such that a portion of the dental bleaching composition is in contact with the patient's tooth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth for a period of time greater than about 2 hours;

(e) removing the dental tray from the patient's teeth.

4. A method for bleaching a patient's teeth comprising the steps of:

(a) obtaining a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of dental bleaching composition;

(b) placing a quantity of dental bleaching composition within the dental tray, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition such that the quantity of dental bleaching composition placed within the dental tray is sufficiently tacky to retain the dental tray positioned against the patient's teeth surfaces without any significant mechanical pressure from the dental tray, said matrix material also having a sufficiently low solubility in saliva such that the matrix material provides for the dental bleaching agent to be available over a period of time greater than about 2 hours to provide bleaching of tooth surfaces;

(c) positioning the dental tray over the patient's teeth surfaces such that at least a portion of the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the patient's teeth for a period of time greater than about 2 hours;

(e) removing the dental tray from the patient's teeth.

5. A method for bleaching a patient's teeth as defined in claim 4, wherein the step of obtaining a dental tray further comprises obtaining a dental tray constructed with reservoirs for holding additional dental bleaching composition such that when the dental tray is positioned over the patient's teeth surfaces, the additional dental bleaching composition within the reservoirs is in contact with the patient's teeth surfaces to be bleached.

6. A method for bleaching a patient's teeth as defined in claim 4, further comprising the step of repeating steps (b) through (e).

7. A method for bleaching a patient's teeth as defined in claim 4, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 5 hours and wherein the dental bleaching agent remains active while the dental tray is positioned over the patient's teeth surfaces.

8. A method for bleaching a patient's teeth as defined in claim 4, wherein the dental tray remains positioned over a patient's teeth for a period of time greater than about 8 hours and wherein the dental bleaching agent remains active while the dental tray is positioned over the patient's teeth surfaces.

9. A dental bleaching composition adapted to be loaded into a dental tray designed for placement over teeth such that the dental bleaching composition will contact tooth surfaces when the dental tray is placed over the teeth, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, and said matrix material including a quantity of water having a weight percent of the total dental bleaching composition in a range from about 10% to about 60%, such that the matrix material has sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that the matrix material is sufficiently sticky to retain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray.

10. A dental bleaching composition adapted to be loaded into a dental tray

designed for placement over teeth such that the dental bleaching composition will contact tooth surfaces when the dental tray is placed over the teeth, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, the matrix material including carboxypolymethylene and water in amounts such that the matrix material

(a) maintains sufficiently high viscosity and low solubility in saliva in order to provide for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces; and

(b) remains sufficiently sticky to retrain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray.

11. A dental bleaching composition adapted to be loaded into a dental tray designed for placement over teeth such that the dental bleaching composition will contact tooth surfaces when the dental tray is placed over the teeth, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including a quantity of carboxypolymethylene or an equivalent thereto, such that (a) said matrix material has sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces, and such that (b) the matrix material is sufficiently sticky to retain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray.

12. A dental bleaching composition as defined in claim 11, wherein the matrix material comprises carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition, or an equivalent thereto.

13. A dental bleaching composition as defined in claim 11, wherein the matrix material comprises carboxypolymethylene in the range from about 4.5% to about 10% by weight of the dental bleaching composition, or an equivalent thereto.

14. A dental bleaching composition as defined in claim 11, wherein the matrix material comprises carboxypolymethylene in the range from about 6% to about 8% by weight of the dental bleaching composition, or an equivalent thereto.

15. A dental bleaching composition as defined in claim 11, wherein the matrix material comprises carboxypolymethylene in the range from about 15% to about 35% by weight of the total quantity of water in the total dental bleaching composition, or an equivalent thereto.

16. A dental bleaching composition as defined in claim 11, wherein the matrix material comprises carboxypolymethylene in the range from about 20% to about 30% by weight of the total quantity of water in the total dental bleaching composition, or an equivalent thereto.

17. A sustained release dental bleaching composition as defined in claim 11,

further comprising a sufficient quantity of a base to adjust the pH of the dental bleaching composition to within the pH range from about 5 to about 7.

18. A sustained release dental bleaching composition as defined in claim 11, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

19. A sustained release dental bleaching composition as defined in claim 11, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

20. A sustained release dental bleaching composition as defined in claim 11, wherein the dental bleaching agent comprises hydrogen peroxide in the range from about 2% to about 10% by weight of the dental bleaching composition.

21. A dental bleaching composition adapted to be loaded into a dental tray designed for placement over teeth such that the dental bleaching composition will contact the tooth surfaces when the dental tray is placed over the teeth, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent;

a quantity of water .having a weight percent of the total dental bleaching composition in the range from about 10% to about 60%;

a quantity of glycerin having a weight percent of the dental bleaching composition in the range from about 20% to about 70%;

a quantity of carboxypolymethylene having a weight percent of the dental bleaching composition in the range from about 3.5% to about 12%; and

a sufficient quantity of the base to adjust the Ph of the dental bleaching composition to within the Ph range from about 5 to about 7, said quantities of water, glycerin, carboxypolymethylene and base together forming a matrix material into which the quantity of dental bleaching agent is dispersed, and wherein said matrix material is sufficiently sticky to retain and hold said dental tray in place over said teeth for a period of time greater than about 2 hours without any significant mechanical pressure from the dental tray, and said matrix material having a sufficiently high viscosity and low solubility in saliva to prevent said matrix material from being significantly diluted in saliva while the tray is worn so that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over said period of time, thereby providing bleaching of the tooth surfaces.

22. A sustained release dental bleaching composition as defined in claim 21, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 3% to about 20% by weight of the dental bleaching composition.

23. A sustained release dental bleaching composition as defined in claim 24, wherein the dental bleaching agent comprises carbamide peroxide in the range from about 4% to about 15% by weight of the dental bleaching composition.

24. A sustained release dental bleaching composition as defined in claim 21, wherein the dental bleaching agent comprises hydrogen peroxide in the range from about 2% to about 10% by weight of the dental bleaching composition.

25. A sustained release dental bleaching composition as defined in claim 21, wherein the quantity of water has a weight percent of the total dental bleaching composition in the range from about 15% to about 40%.

26. A sustained release dental bleaching composition as defined in claim 21,

wherein the quantity of glycerine has a weight percent of the dental bleaching composition in the range from about 30% to about 60%.

27. A sustained release dental bleaching composition as defined in claim 21, wherein the quantity of carboxypolymethylene has a weight percent of the dental bleaching composition in the range form about 4.5% to about 10%.

28. A sustained release dental bleaching composition as defined in claim 21, wherein the quantity of carboxypolymethylene has a weight percent of the dental bleaching composition in the range form about 6% to about 8%.

29. A sustained release dental bleaching composition as defined in claim 21, wherein the quantity of carboxypolymethylene has a weight percent in the range from about 15% to about 35% by weight of the total quantity of water in the total dental bleaching composition.

30. A sustained release dental bleaching composition as defined in claim 21, wherein the quantity of carboxypolymethylene has a weight percent in the range from about 20% to about 30% by weight of the total quantity of water in the dental bleaching composition.

31. A sustained release dental bleaching composition as defined in claim 21, wherein the carboxypolymethylene.

32. A sustained release dental bleaching composition as defined in claim 31, wherein the carboxypolymethylene comprises Carbopol 934P.

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L6: Entry 1 of 2 File: USPT Apr 25, 1995

US-PAT-NO: 5409631
DOCUMENT-IDENTIFIER: US 5409631 A

TITLE: Dental bleaching compositions and methods for bleaching teeth surfaces

DATE-ISSUED: April 25, 1995

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products	So. Jordan	UT			02

APPL-NO: 07/ 797419 [PALM]
DATE FILED: November 22, 1991

PARENT-CASE:
BACKGROUND 1. Related Application This application is a divisional of application Ser. No. 07/553,168, filed Jul. 13, 1990, now U.S. Pat. No. 5,098,303, which is a continuation-in-part of copending patent application Ser. No. 07/497,934, filed Mar. 22, 1990, in the name of Dan E. Fischer and entitled "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES," now abandoned. Each of these is incorporated herein by specific reference.

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FIELD-OF-SEARCH: 252/186.27, 252/186.28, 252/186.29, 252/186.25, 252/186.26, 106/35

PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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ART-UNIT: 223

PRIMARY-EXAMINER: Stoll; Robert L.

ASSISTANT-EXAMINER: Anthony; Joseph D.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

13 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 2. The Field of the Invention

2 The present invention relates to improved dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity dental compositions, such as tooth bleaching compositions, having significantly improved effectiveness and sustained release activity. The dental compositions may advantageously be used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

3 3. The Prior Art

4 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

5 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (3) expectorate any excess bleaching solution, (4) change the bleaching solution every 1 to 2.5 hours, and (5) remove the tray during meals. A few recommend wearing the tray during the night.

6 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been recommended and prescribed by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended usage. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

7 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

8 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that either the bleaching agent must be frequently replaced during the day or the treatment extend for several weeks or months. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

9 Since current home-use bleaching agents must be frequently replenished, the user necessarily ingests large volumes of the bleaching agent. In many cases, ingestion of the bleaching agent causes sore throats. Some researchers have even suggested that long term repeated ingestion of large quantities of carbamide peroxide may be carcinogenic. Therefore, patient ingestion of dental bleaching compositions should be minimized.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patient's. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a saturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them, gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 Recent experimental tests have compared one dental bleaching composition within the scope of the present invention with some commercially available dental bleaching compositions. All tested bleaching compositions had the same concentration of active ingredient (10% carbamide peroxide). The tests only examined bleaching effectiveness and did not consider increased effectiveness resulting from sustained release properties. The experimental results indicate that the present bleaching composition provides significantly greater effectiveness than the other tested bleaching compositions, irrespective of its sustained release properties. It is, therefore, an object of the present invention to provide highly effective dental bleaching compositions.

27 An additional object of the present invention is to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

28 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

29 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

30 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

31 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

FIG. 5 is a graph illustrating the results of Example 10.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the trade name "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. Some commercially available dental bleaching compositions contain low concentrations of carbopol. Importantly, it has been found that by preparing saturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of nonaqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, Carbopol 940 appears to dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 Another important advantage of the concentrated carboxypolymethylene compositions within the scope of the present invention is that on contact with saliva, the composition becomes initially firmer. As a result, a seal around

the periphery of the dental tray is formed where the composition is in contact with saliva which keeps the remainder of the composition in contact with the teeth surfaces entrapped and "sealed" therein. The firmer material at the tray periphery also fills the minor discrepancies of the tray-to-tooth fit.

11 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental composition will be maintained over a greater period of time in a high salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene, relatively speaking, but still higher than typical concentrations, so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

12 The concentrated carboxypolymethylene composition also has a tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition not only keeps the composition within the reservoirs, but also retains the tray against the patient's teeth, thereby permitting softer, thinner, and more flexible tray materials to be used. It has been found that if too much carboxypolymethylene is used, the tackiness can decrease and the composition encumbers complete tray insertion.

13 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine enables the large quantities of carboxypolymethylene to be dispersed easier in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 40% to about 60% by weight.

14 In addition to functioning as a humectant, the glycerine also provides some flavor sweetening enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycols or other polyols.

15 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range form about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

16 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used; the use concentrated sodium hydroxide (50% NaOH) is one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

17 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental

tray after an extended period of time, such as at the end of the night.

18 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention, gravity is not sufficient.

19 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

20 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor and control how many doses the patient has received and used.

21 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

22 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a syringe applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

23 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.035 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patient's will find 0.035 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient's suspected of being bruxers or hard biters may require a 0.06 inch tray material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

24 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

25 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the

tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

26 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

27 To achieve most rapid results, it is recommended to use sustained release bleaching agent within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase is effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs than with conventional trays without reservoirs.

28 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

29 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

30 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

31 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

32 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

33 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

34 If patient instructions are followed, more predictable results are obtained in

days rather than weeks. Also, less total volume of bleaching agent is used (from 1/10 to 1/20 the volume of conventional peroxide solutions). As a result, less bleaching agent is swallowed by the patient.

35 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 2 to 4 three hour treatments, or 1 or 2 night-time treatments. One typical sustained release fluoride composition within the scope of the present invention contains 0.5% sodium fluoride in a high viscosity gel.

36 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

37 EXAMPLE 1

38 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight %
Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

39 The Carbopol 934P was obtained from B. F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

40 The foregoing procedure produced in a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

41 EXAMPLE 2

42 A sustained release dental bleaching composition within the scope of the present invention was made according to the procedure of Example 1, except that the ingredients were combined in the following amounts:

Ingredient	Weight	Weight %

Carbamide peroxide	1150	10
Water	2030	18
Glycerine	6660	59
Carbopol 934P	830	7
Sodium hydroxide	650	6

43 The foregoing procedure resulted in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.6%. The composition possessed a high viscosity and excellent sustained release teeth bleaching activity.

44 EXAMPLE 3

45 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

46 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

47 EXAMPLE 4

48 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

49 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained

release teeth bleaching activity.

50 EXAMPLE 5

51 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

52 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

53 EXAMPLE 6

54 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

55 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

56 EXAMPLE 7

57 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent

Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

58 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

59 EXAMPLE 8

60 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

61 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

62 EXAMPLE 9

63 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

64 The foregoing ingredients are mixed according to the procedure of example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained about 1.1% so that the free fluoride ion

concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

65 EXAMPLE 10

66 In this example, the in vitro brightening effect of two commercially available bleaching agents was measured and compared with the dental bleaching composition prepared according to the procedure of Example 1. Thirty-six (36) extracted anterior and premolar teeth without caries or restorations were randomly divided into four (4) groups and mounted. A thermoplastic splint was made for each group. In addition to the dental bleaching agent of Example 1, Denta-Lite (manufactured by Challenge Products, Osage Beach, Mo.) and Proxigel (manufactured by Reed & Carnrick, Piscataway, N.J.) were tested. All of bleaching agents contained 10% carbamide peroxide as the active ingredient. Groups 1-3 were treated with the bleaching agents and group 4 was used as a control and bathed in sterile distilled water.

67 Bleaching agent was placed into a splint and replaced every 3 hours during the day and after 8 hours at night. The treatment continued for a period of 2 weeks averaging a minimum of 18 hours of bleaching per day. All teeth and splints were brushed and rinsed with water before replacing bleaching agents.

68 Measurements were taken using a Pentax photo spot meter, measuring brightness changes occurring at intervals of 24 hours, 72 hours, 7 days, and 14 days. The photo spot meter was equipped with an analog meter and the ability to read in 0.1 value variations. The meter was attached to a measuring apparatus which reflected two light sources at a 60 degree deflection angle toward the crown of the tooth being measured. A rheostat controlled the light sources to allow a constant emittance during each measurement. The data were analyzed using a 2-way ANOVA and Duncan's multiple range test.

69 Photographs were taken before, at 72 hours, and at 14 days following bleaching. A 35 mm single reflex camera with a macro lens and a 2x diopter was used for all photography.

70 The results of this Example are reported in Table 1 and illustrated graphically in FIG. 5. They indicate that the dental bleaching composition within the scope of the present invention is over 50% more effective than the two commercially available dental bleaching agents having the same concentration of active ingredient. In fact, the bleaching agent of Example 1 provided greater whitening in just 3 days of treatment than the other bleaching agents did after two weeks of treatment.

71 It is important to recognize that the results of this Example to not address the impact of saliva on the effectiveness of the dental bleaching agents. The sustained release characteristics of the dental bleaching agent within the scope of the present invention were not addressed by this Example. Therefore, the effectiveness of the present invention can be expected to be even greater than the prior art bleaching agents when the sustained release activity is considered.

TABLE 1

Bleaching Effect of 10% Carbamide Peroxide Value Changes:
Means and standard deviations

Bleaching Agent	No.	24 Hrs.	72 Hrs.	7 Days	14 Days
Water	9	0	0	0	0

Example 1	9	.34(.06)	.56(.08)	.60(.09)	.67(.13)
Denta-Lite	9	.22(.08)	.35(.11)	.38(.10)	.48(.13)
Proxigel	9	.22(.07)	.33(.12)	.34(.11)	.40(.10)

72 Although much of the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other dental compositions, whether sustained release or not, may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the such dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

73 In some cases, the dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

74 From the foregoing, it will be appreciated the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

75 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

76 It will be further appreciated that the present invention provides dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

77 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

78 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A dental bleaching composition adapted to be loaded into a dental tray designed for placement over teeth such that the dental bleaching composition will contact tooth surfaces when the dental tray is placed over the teeth, said dental bleaching composition comprising:

a quantity of dental bleaching agent that is physiologically compatible and capable of bleaching tooth surfaces in contact with said dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, said matrix material including carboxypolymethylene or an equivalent thereto in a range from about 3.5% to about 12% by weight of the dental bleaching composition such that (a) said matrix material has sufficiently high viscosity and low solubility in saliva that the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours, thereby providing bleaching of the tooth surfaces, and such that (b) the matrix material is sufficiently sticky to retain and hold said dental tray in place over said teeth for a period of time greater than about 3 hours without any significant mechanical pressure from the dental tray.

2. A dental bleaching composition as defined in claim 1, wherein the carboxypolymethylene or equivalent thereto is included in a range from about 4.5% to about 10% by weight of the dental bleaching composition.

3. A dental bleaching composition as defined in claim 1, wherein the carboxypolymethylene or equivalent thereto is included in a range front about 6% to about 8% by weight of the dental bleaching composition.

4. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition includes a quantity of water and wherein the matrix material comprises carboxypolymethylene in a range from about 15% to about 35% by weight of the quantity of water in the dental bleaching composition.

5. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition includes a quantity of water and wherein the matrix material comprises carboxypolymethylene in a range from about 20% to about 30% by weight of the quantity of water in the dental bleaching composition.

6. A dental bleaching composition as defined in claim 1, comprising a sufficient quantity of a base to adjust the pH of the dental bleaching composition to within a pH range from about 5 to about 7.

7. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide in a range from about 3% to about 20% by weight of the dental bleaching composition.

8. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide in a range from about 4% to about 15% by weight of the dental bleaching composition.

9. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises hydrogen peroxide in a range from about 2% to about 10% by weight of the dental bleaching composition.

10. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition includes a quantity of water having a concentration in a range from about 15% to about 40% by weight of the dental bleaching composition.

11. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition includes a quantity of glycerine having a concentration

in a range from about 40% to about 60% by weight of the dental bleaching composition.

12. A dental bleaching composition as defined in claim 1, wherein the carboxypolymethylene comprises a pharmaceutical grade carboxypolymethylene.

13. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition is dispensed in unit dosage quantities.

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

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PARENT-CASE:
RELATED APPLICATIONS This application is a continuation of application Ser. No. 08/378,315, filed Jan. 25, 1995, in the name of Dan E. Fischer, D.D.S., for "ANTICARIOGENIC AND ANTIMICROBIAL DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES", which is a file wrapper continuation of application Ser. No. 08/099,247, filed Jul. 28, 1993, for "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES" (abandoned), which is a file wrapper continuation of application Ser. No. 07/985,700, filed Dec. 2, 1992, (abandoned), which is a file wrapper continuation of U.S. application Ser. No. 07/718,210, filed Jun. 20, 1991, (abandoned), which is a divisional of U.S. application Ser. No. 07/497,934, filed Mar. 22, 1990. (abandoned).

INT-CL: [06] A61 K 7/16, A61 C 5/00

US-CL-ISSUED: 424/49; 424/53, 514/900, 514/944, 433/215
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FIELD-OF-SEARCH: 424/49, 424/52, 424/53, 424/673, 252/315.01, 252/514, 514/900, 514/944, 433/215

PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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Deposition (Group) of Coastal Dental Study Club, Civil Action No. 91-1406 WJR (Sx) (C.D. Cal.).
Declaration of Dr. David H. Freshwater (2), Civil Action No. 91-1406 WJR (Sx) (C.D.Cal.).
Deposition of Dr. David H. Freshwater with Exhibits, Civil Action No. 91-1406 WJR (Sx)(C.D. Cal.).
Deposition of Dr. Van B. Haywood with Exhibits, Civil Action No. 91-1406 WJR (Sx) (C.D. Cal.).
Declaration of Dr. William W. Klusmeier(2), Civil Action No. 91-1406 WJR (Sx)(C.D. Cal.).
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Declaration of Dr. Jerry Wagner, Civil Action No. 91-1406 WJR(Sx)(C.D. Cal.).
Deposition of Dr. Jerry Wagner, Civil Action No. 91-1406 WJR (Sx) (C.D. Cal.).
Deposition of Harry F. Albers with Exhibits, Civil Action No. 2:95CV 0163W (D. Utah).
Deposition of Dr. Van B. Haywood with Exhibits, Civil Action No. 2:95CV 0163W (D. Utah).
Expert Report of Dr. Van B. Haywood, Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Harry F. Albers (Direct), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Dan E. Fischer (Direct and Rebuttal), Civil Action No. 2:95CV 0163 W (D. Utah).
Trial Testimony of Roger Hicks (Rebuttal), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Bryan D. Tart (Direct), Civil Action No. 2:95CV 0163 W (D. Utah).

Trial Testimony of Garold S. Yost (Rebuttle), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Wayne Smith Gundry (Direct), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Walter O. Dixon (Direct), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Exhibits, Civil Action No. 2:95CV 0163W (D. Utah).

ART-UNIT: 152

PRIMARY-EXAMINER: Bawa; Raj

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release

dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

14 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Relevant Technology

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (c) expectorate any excess bleaching solution, (d) change the bleaching solution every 1 to 2.5 hours, and (e) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth

bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patients. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them; gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter

of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials that are preferably safe for oral use do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental compositions will be maintained over a greater period of time in a highly salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene glycol, sorbitol, some

polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range from about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use of concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention; gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line or margin 16. The finished coating is preferably about 1/2 mm thick. It is particularly important

when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patients will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patients suspected of being bruxers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agents within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase in effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs compared to conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to

rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

37 The Carbopol 934P was obtained from B.F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced a sustained release dental bleaching composition which was placed in a dental tray such as that described in

connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of Example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained at about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as

chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated that the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by U.S. Letters Patent is:

1. A method for bleaching a person's teeth comprising the following steps:

(a) obtaining a dental tray configured to cover a person's tooth surfaces to be bleached and configured to hold a quantity of a dental bleaching composition, the dental tray being configured to exert no significant pressure on the person's teeth and gums;

(b) placing a quantity of the dental bleaching composition within the dental tray, wherein the dental bleaching composition comprises a mixture which includes carboxypolymethylene, including any carboxypolymethylene that has been neutralized, and has a stickiness and resistance to dilution by saliva so that dental bleaching composition is able to retain and hold the dental tray positioned over the person's teeth for a period of time of at least about two hours;

(c) positioning the dental tray over the person's teeth such that a portion of

the dental bleaching composition is in contact with the person's tooth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the person's teeth for a desired period of time, the dental bleaching composition remaining active during at least a portion of the time while the dental tray is positioned over the person's teeth; and

(e) removing the dental tray from the person's teeth.

2. A method for bleaching a person's teeth as defined in claim 1, wherein the step of obtaining a dental tray further comprises obtaining a dental tray constructed with one or more reservoirs for holding additional dental bleaching composition so that when the dental tray is positioned over the person's teeth the additional dental bleaching composition within the reservoirs is in contact with the person's tooth surfaces to be bleached.

3. A method for bleaching a person's teeth as defined in claim 1, further comprising repeating steps (b) through (e) one or more iterations.

4. A method for bleaching a person's teeth as defined in claim 1, wherein the dental tray remains positioned over the person's teeth for a period of time greater than about five hours and wherein the dental bleaching composition remains active during at least a portion of the time while the dental tray is positioned over the person's teeth.

5. A method for bleaching a person's teeth as defined in claim 1, wherein the dental tray remains positioned over the person's teeth for a period of time greater than about eight hours and wherein the dental bleaching composition remains active during at least a portion of the time while the dental tray is positioned over the person's teeth.

6. A method for bleaching a person's teeth as defined in claim 2, wherein the one or more reservoirs are constructed in the dental tray so as to cover the labial aspect of the person's teeth.

7. A method for bleaching a person's teeth as defined in claim 1, wherein the dental tray comprises a soft polymer having a preformed thickness in a range from about 0.04 inches to about 0.06 inches.

8. A method for bleaching a person's teeth as defined in claim 1, wherein the dental bleaching composition comprises a dental bleaching agent dispersed within a matrix material that provides the stickiness and resistance to dilution by saliva.

9. A method for bleaching a person's teeth as defined in claim 8, wherein the dental bleaching agent comprises carbamide peroxide.

10. A method for bleaching a person's teeth as defined in claim 8, wherein the dental bleaching agent comprises hydrogen peroxide.

11. A method for bleaching a person's teeth as defined in claim 1, wherein a portion of the carboxypolymethylene has been neutralized with a quantity of a base.

12. A method for bleaching a person's teeth as defined in claim 11, wherein the quantity of the base is added to neutralize the carboxypolymethylene to within a pH in a range from about 5 to about 7.

13. A method for bleaching a person's teeth comprising:

(a) obtaining a dental tray configured to cover a person's tooth surfaces to be bleached and configured to hold a quantity of a dental bleaching composition;

(b) placing a quantity of the dental bleaching composition within the dental tray, the dental bleaching composition including:

(1) a quantity of a dental bleaching agent capable of bleaching tooth surfaces; and

(2) a matrix material into which the bleaching agent is dispersed, wherein the matrix material comprises carboxypolymethylene, including any carboxypolymethylene that has been neutralized, in a range from about 3.5% to about 12% by weight of the dental bleaching composition;

(c) positioning the dental tray over the person's teeth so that a portion of the dental bleaching composition is in contact with the person's tooth surfaces to be bleached;

(d) allowing the dental tray to remain positioned over the person's teeth for a desired period of time, the dental bleaching agent remaining active during at least a portion of the time while the dental tray is positioned over the person's teeth; and

(e) removing the dental tray from the person's teeth.

14. A method for bleaching a person's teeth comprising:

(a) obtaining a dental tray configured to cover a person's tooth surfaces to be bleached and configured to hold a quantity of a dental bleaching composition, the dental tray being trimmed to terminate at or below the person's gum line and configured to exert no significant pressure on the person's teeth and gums;

(b) placing a quantity of the dental bleaching composition within the dental tray, the dental bleaching composition comprises a mixture that includes carboxypolymethylene, including any carboxypolymethylene that has been neutralized, and having a stickiness and resistance to dilution by saliva so that dental bleaching composition is able to retain and hold the dental tray positioned over the person's teeth for a period of time of at least about two hours;

(c) positioning the dental tray over the person's teeth so that a portion of the dental bleaching composition is in contact with the person's tooth surfaces to be bleached, the stickiness of the dental bleaching composition retaining the dental tray in place without significant orthodontic pressure from the dental tray;

(d) allowing the dental tray to remain positioned over the person's teeth for a desired period of time, the dental bleaching agent remaining active during at least a portion of the time while the dental tray is positioned over the person's teeth; and

(e) removing the dental tray from the person's teeth.

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L7: Entry 1 of 2 File: USPT May 5, 1998

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TITLE: Dental bleaching compositions including a sticky matrix material

DATE-ISSUED: May 5, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

APPL-NO: 08/ 722553 [PALM]
DATE FILED: September 27, 1996

PARENT-CASE:
RELATED APPLICATIONS This application is a continuation of copending application Ser. No. 08/378,315 filed Jan. 25, 1995 in the name of Dan E. Fischer, D.D.S., for "ANTICARIOGENIC AND ANTIMICROBIAL DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES", which is a file wrapper continuation of copending application Ser. No. 08/099,247 filed Jul. 28, 1993 for "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES" (abandoned), which is a file wrapper continuation of copending application Ser. No. 07/985,700 filed Dec. 2, 1992 (abandoned), which is a file wrapper continuation of copending U.S. application Ser. No. 07/718,210 filed Jun. 20, 1991 (abandoned), which is a divisional of U.S. application Ser. No. 07/497,934, filed Mar. 22, 1990 (abandoned).

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PRIOR-ART-DISCLOSED:

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ART-UNIT: 333

PRIMARY-EXAMINER: Lucchesi; Nicholas D.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

23 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Relevant Technology

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the hlabial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (c) expectorate any excess bleaching solution, (4) change the bleaching solution every 1 to 2.5 hours, and (5) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been

used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Manv patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patients. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them; gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient

compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3A designates a cut-away view along line 3A-3A of FIG. 3.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental trav having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials that are preferably safe for oral use do not readily dissolve in saliva and do not react with or inactivate the dental bleaching agent. One

currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental compositions will be maintained over a greater period of time in a highly salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is

recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, glycol sorbitol, some polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range from about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use of concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental

trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line or margin 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient's suspected of being bruxers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agents within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase in effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs compared to conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release

bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2	gm	10%
Water	27.5	gm	21%
Glycerine	74.6	gm	57%
Carbopol 934P	9.5	gm	7%
Sodium hydroxide (50%)	6.5	gm	5%

37 The Carbopol 934P was obtained from B.F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight		Weight Percent
Sodium fluoride	52	gm	1.1%
Water	1000	gm	21.5%
Glycerine	2980	gm	64.1%
Carbopol 934P	380	gm	8.2%
Sodium hydroxide (50%)	238	gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained at about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated that the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by united states letters patent is:

1. A dental bleaching composition comprising:

a dental bleaching agent capable of bleaching tooth surfaces in contact with

the dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, wherein the matrix material comprises carboxypolymethylene, which includes any reaction products of carboxypolymethylene, wherein the matrix material has a stickiness and resistance to dilution by saliva such that when the dental composition is placed within a dental tray and the dental tray is positioned over the teeth the dental composition will retain the dental tray in position over the teeth for at least about 2 hours without significant pressure exerted by the dental tray, thereby allowing the bleaching agent to contact the tooth surfaces while the dental tray is held in place by the dental composition.

2. A dental bleaching composition as defined in claim 1, wherein the carboxypolymethylene includes at least partially neutralized carboxypolymethylene.

3. A dental bleaching composition as defined in claim 2, wherein the matrix material further includes added water.

4. A dental bleaching composition as defined in claim 2, wherein the matrix material further includes glycerine.

5. A dental bleaching composition as defined in claim 1, further comprising a quantity of a base sufficient to adjust the pH of the dental bleaching composition to within a pH range of about 5 to about 7.

6. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises carbamide peroxide.

7. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent comprises hydrogen peroxide.

8. A dental bleaching composition as defined in claim 1, further including sodium fluoride.

9. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition is sufficiently sticky such that it can retain the dental tray in place over the teeth for at least about 3 hours without significant pressure exerted by the dental tray.

10. A dental bleaching composition as defined in claim 1, wherein the dental bleaching composition is adapted to be delivered by a syringe.

11. A dental bleaching composition as defined in claim 1, wherein the matrix material further includes polyethylene glycol.

12. A dental bleaching composition as defined in claim 1, wherein the matrix material further includes a mixture of glycerin and polyethylene glycol.

13. A dental bleaching composition comprising:

a dental bleaching agent capable of bleaching tooth surfaces in contact with the dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, wherein the matrix material includes carboxypolymethylene that has been neutralized with a base such that the dental bleaching composition has a pH in a range from about 5 to about 7, wherein the matrix material has a stickiness and resistance to dilution by saliva such that when the dental composition is placed within a dental tray and the dental tray is positioned over the teeth the dental composition will retain the dental tray in position over the teeth for at least about 2 hours without significant pressure exerted by the dental tray, thereby allowing the bleaching agent to contact the tooth surfaces while the dental

tray is held in place by the dental composition.

14. A dental bleaching composition as defined in claim 13, wherein the dental bleaching agent comprises carbamide peroxide.

15. A dental bleaching composition as defined in claim 13, wherein the dental bleaching agent comprises hydrogen peroxide.

16. A dental bleaching composition as defined in claim 13, wherein the base comprises triethanolamine.

17. A dental bleaching composition as defined in claim 13, wherein the base comprises sodium hydroxide.

18. A dental bleaching composition comprising:

a dental bleaching agent capable of bleaching tooth surfaces in contact with the dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, the matrix material including water, glycerin, carboxypolymethylene, which includes reaction products of carboxypolymethylene, and a base such that the dental bleaching composition has a pH in a range from about 5 to about 7 and such that the matrix material has a stickiness and resistance to dilution by saliva so that when the dental composition is placed within a dental tray and the dental tray is positioned over the teeth the dental composition will retain the dental tray in position over the teeth for at least about 2 hours without significant orthodontic pressure exerted by dental try, thereby allowing the bleaching agent to contact the tooth surfaces while the dental tray is held in place by the dental composition.

19. A dental bleaching composition as defined in claim 18, wherein the base comprises triethanolamine.

20. A dental bleaching composition as defined in claim 18, wherein the base comprises sodium hydroxide.

21. A dental bleaching composition comprising:

a dental bleaching agent capable of bleaching tooth surfaces in contact with the dental bleaching agent; and

a matrix material into which the dental bleaching agent is dispersed, wherein the matrix material comprises polyethylene glycol and carboxypolymethylene, including any reaction products of carboxypolymethylene, wherein the matrix material has a stickiness and resistance to dilution by saliva such that when the dental composition is placed within a dental tray and the dental tray is positioned over the teeth the dental composition will retain the dental tray in position over the teeth for at least about 2 hours without significant pressure exerted by the dental tray, thereby allowing the bleaching agent to contact the tooth surfaces while the dental tray is held in place by the dental composition.

22. A dental bleaching composition as defined in claim 7, wherein the matrix material further includes water.

23. A dental bleaching composition as defined in claim 21, wherein the matrix material further includes glycerin.

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L8: Entry 1 of 2 File: USPT Jun 2, 1998

US-PAT-NO: 5759038
DOCUMENT-IDENTIFIER: US 5759038 A

TITLE: Dental kit for applying sticky dental bleaching compositions to a person's teeth

DATE-ISSUED: June 2, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT	84093	

APPL-NO: 08/ 721048 [PALM]
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PARENT-CASE:
RELATED APPLICATIONS This application is a continuation of copending application Ser. No. 08/378,315 filed Jan. 25, 1995 in the name of Dan E. Fischer, D.D.S., for "ANTICARIOGENIC AND ANTIMICROBIAL DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES", which is a file wrapper continuation of application Ser. No. 08/099,247 filed Jul. 28, 1993 for "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES" (abandoned), which is a file wrapper continuation of application Ser. No. 07/985,700 filed Dec. 2, 1992 (abandoned), which is a file wrapper continuation of U.S. application Ser. No. 07/718,210 filed Jun. 20, 1991 (abandoned), which is a divisional of U.S. application Ser. No. 07/497,934, filed Mar. 22, 1990 (abandoned).

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Declaration of Dr. Phil S. Sanders, Civil Action No. 91-406 WJR (Sx) (C.D. Cal.).
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ART-UNIT: 165

PRIMARY-EXAMINER: Bawa; Raj

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release.

The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

20 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 The Relevent Technology

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (c) expectorate any excess bleaching solution, (d) change the bleaching solution every 1 to 2.5 hours, and (e) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9. Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patients. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix

materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them; gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved

dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 3A is a close-up view of circular section 3A--3A.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix that materials that are preferably safe for oral use do not readily dissolve in saliva and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B.F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental

compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition..

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental compositions will be maintained over a greater period of time in a highly salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene glycol, sorbitol, some polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range from about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use of concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention; gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 1 1/4 mm to about 1 1/2 mm from gingival line or margins 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal

edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patients will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patients suspected of being bruxers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agents within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase in effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs compared to conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

37 The Carbopol 934P was obtained from B.F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent

examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of Example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained at about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal

pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated that the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A dental kit for manufacturing a dental tray incorporating one or more reservoirs therein and for applying a dental composition to a person's teeth, the kit comprising:

(a) a thin, flexible preformed polymeric sheet for forming a dental tray from a stone cast of the person's teeth;

(b) a coating composition capable of being applied to the stone cast in a flowable state and then hardening so that upon removal of the formed dental tray from the stone cast one or more reservoirs are formed within the dental tray for holding a quantity of the dental composition therein; and

(c) a dental composition for loading into the dental tray.

2. A dental kit as defined in claim 1, wherein the dental composition includes a sticky matrix material comprising carboxypolymethylene, including any

carboxypolymethylene that has been neutralized.

3. A dental kit as defined in claim 2, wherein the carboxypolymethylene has been neutralized to a pH in a range from about 5 to about 7.

4. A dental kit as defined in claim 1, wherein the dental composition has a stickiness and resistance to dilution by saliva for retaining the dental tray when positioned over the person's teeth for at least about 2 hours without significant pressure from the dental tray.

5. A dental kit as defined in claim 1, wherein the dental composition includes a dental bleaching agent.

6. A dental kit as defined in claim 1, wherein the dental composition includes an anticariogenic agent.

7. A dental kit as defined in claim 1, wherein the dental composition includes an antimicrobial agent.

8. A dental kit as defined in claim 1, wherein the polymeric sheet comprises a soft vinyl polymer.

9. A dental kit as defined in claim 1, wherein the polymeric sheet has a thickness in a range from about 0.04 inch to about 0.06 inch.

10. A dental kit as defined in claim 1, wherein the dental kit further includes an alginate composition for making an impression of the person's teeth.

11. A dental kit as defined in claim 10, wherein the dental kit further includes a composition for making a stone cast of the person's teeth from the alginate impression.

12. A dental kit as defined in claim 1, wherein the coating composition is light curable.

13. A dental kit for manufacturing a dental tray incorporating one or more reservoirs therein and for applying a dental composition to a person's teeth, the kit comprising:

a. a thin, flexible preformed polymeric sheet for forming a dental tray from a stone cast of the person's teeth;

b. a coating composition capable of being applied to the stone cast in a substantially state and then hardening so that upon removal of the formed dental tray from the stone cast one or more reservoirs are formed within the dental tray for holding a quantity of the dental composition therein; and

c. one or more syringes for delivery of the dental composition into the dental tray.

14. A dental kit as defined in claim 13, wherein the one or more syringes are adapted for holding a unit dose of the dental composition.

15. A dental kit for manufacturing a dental tray incorporating one or more reservoirs therein and for applying a dental composition to a person's teeth, the kit comprising:

a. a composition for taking an impression of at least a portion of the person's teeth;

b. a composition capable of forming a stone cast from the impression of at least a portion of the person's teeth;

c. a thin, flexible preformed polymeric sheet for forming a dental tray from the stone cast of at least a portion of the person's teeth;

d. a light curable resin capable of being applied to the stone cast and then hardening when exposed to light so that upon removal of the formed dental tray from the stone cast one or more reservoirs are formed within the dental tray for holding a quantity of the dental composition therein;

e. a sticky dental composition adapted for loading into the dental tray; and

f. one or more syringes for delivery of the dental composition into the dental tray.

16. A dental kit as defined in claim 15, wherein the one or more syringes are adapted for holding a unit dose of the dental composition.

17. A dental kit for manufacturing a dental tray incorporating one or more reservoirs therein and for applying a dental bleaching composition to a person's teeth, the kit comprising:

a. a composition for taking an impression of at least a portion of the person's teeth;

b. a composition capable of forming a stone cast from the impression of at least a portion of the person's teeth;

c. a thin, flexible preformed polymeric sheet for forming a dental tray from the stone cast of at least a portion of the person's teeth,

d. a light curable resin capable of being applied to the stone cast and then hardening when exposed to light so that upon removal of the formed dental tray from the stone cast one or more reservoirs are formed within the dental tray for holding a quantity of the dental composition therein;

e. a dental bleaching composition adapted for loading into the dental tray; and

f. one or more syringes each containing a quantity of the bleaching composition for delivery of the dental composition into the dental tray.

18. A dental kit as defined in claim 17, wherein the one or more syringes are adapted for holding a unit dose of the dental bleaching composition.

19. A kit as defined in claim 1, wherein the coating composition is a light-curable resin that substantially hardens when exposed to light.

20. A kit as defined in claim 13, wherein the coating composition is a light-curable resin that substantially hardens when exposed to light.

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L8: Entry 2 of 2 File: USPT Jun 2, 1998

US-PAT-NO: 5759037
DOCUMENT-IDENTIFIER: US 5759037 A

TITLE: Methods for manufacturing dental trays having thin walls for increased comfort

DATE-ISSUED: June 2, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT	84093	

US-CL-CURRENT: 433/215; 424/49, 433/216, 433/217.1, 433/226, 514/944

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

24 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

WEST

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L10: Entry 5 of 13 File: USPT Nov 6, 2001

US-PAT-NO: 6312666
DOCUMENT-IDENTIFIER: US 6312666 B1

TITLE: Methods of whitening teeth

DATE-ISSUED: November 6, 2001

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Oxman; Joel D.	St. Louis Park	MN		
Trom; Matt C.	Cottage Grove	MN		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
3M Innovative Properties Company	St. Paul	MN			02

APPL-NO: 09/ 190541 [PALM]
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US-CL-ISSUED: 424/49; 424/53, 433/215
US-CL-CURRENT: 424/49; 424/53, 433/215

FIELD-OF-SEARCH: 424/49-88, 433/215

PRIOR-ART-DISCLOSED:

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ART-UNIT: 164

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

Dental whitening compositions are provided that have the capability of undergoing an increase in viscosity in response to an increase in temperature. In a preferred embodiment, the compositions also have the ability to reverse their viscosity in response to a decrease in temperature.

20 Claims, 1 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 1

BRIEF SUMMARY:

1 FIELD OF THE INVENTION

2 This invention relates to dental whitening or brightening compositions having viscosities capable of responding to a change in temperature. The invention also relates to methods of whitening or brightening teeth surfaces using the composition, particularly methods of whitening or brightening teeth by dispensing the composition into a dental tray or directly onto tooth surfaces and keeping it in the mouth for some period of time.

3 BACKGROUND

4 Home teeth whitening systems have been available since the late 1980's, acquired either through a dental professional or over-the-counter. Prior to these systems, persons desiring whiter or brighter teeth were subjected to various heat or light activated systems provided by their dental practitioner in the dental chair. Typically, these practices involved the dental practitioner applying a hydrogen peroxide solution on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat to the applied solution to effectuate oxidation. Such oxidation removed discoloration from the tooth surfaces.

5 With the greater consumer demand for cosmetically enhancing products, aesthetic dentistry has correspondingly grown. The demand for these products also created interest in products which could be administered at a more convenient time and place, and/or with less equipment. Thus, numerous products have since been developed which provide a person with the means to treat and whiten his or her teeth in the privacy and convenience of the home.

6 Generally, to begin the whitening process, a user is provided with a dental tray, either by a dental practitioner or as part of a purchased dental whitening kit. The tray is intended to retain the whitening composition at the desired location(s) and maintain contact between the tooth surface and the whitening composition. When the treatment involves a dental practitioner, the dental tray is typically custom fitted to the user's personal denition. Some dental practitioners may choose to have selectively enlarged tooth-treating compartments or reservoirs fabricated within the dental tray which are adapted to receive a sufficient amount of tooth whitening composition. The purpose for having such reservoirs is to provide more whitening composition and to ensure, if desired, long-lasting exposure of the teeth to the whitening agent. The dental tray loaded with whitening composition is typically worn by the patient for some extended period of time (e.g. 30 minutes to 8 hours), depending on the degree of discoloration the user desires to remove. This treatment is repeated over a sufficient period of time to effect the tooth whitening and bleaching process.

7 Whitening compositions are generally formulated with thickening rheological modifiers such as carboxypolymethylene, cellulosic polymers, or fumed silicas in order for the compositions to be provided as a thickened composition. For example, Pellico, U.S. Pat. No. 5,361,000 is directed to dental whitening compositions thickened with glycerin and carboxypolymethylene. Pellico, U.S. Pat. No. 5,718,886 discloses a stabilized anhydrous dental whitening composition utilizing Xanthum gum as a thickening agent.

8 During the intraoral application of a tray and whitening composition, a system can increase from ambient temperature of about 22-25.degree. C., to about 37.degree. C. As a result of this temperature rise, the whitening composition may have a tendency to decrease in viscosity and become more flowable. In addition, the composition may also become diluted from saliva moving in and out of the tray, resulting in dilution of the composition. This thinning and viscosity decrease creates a tendency for the composition and thus the whitening agent, to flow out of the tray, resulting in a reduced amount of whitening composition available for treatment at the target location for the desired length of time.

9 To overcome the effect of temperature and salivation, a series of patents by Fischer, namely U.S. Pat. Nos. 5,098,303; 5,234,342; 5,376,006; 5,409,631; 5,770,105; 5,725,843; and 5,746,598 disclose teeth whitening compositions characterized with high viscosity and stickiness to minimize dilution from saliva and prolong the period of time the whitening agent is in contact with the teeth surfaces. These patents describe the use of high concentrations of carboxypolymethylene to provide the high viscosity characteristic of the whitening composition as it is stored in its container.

10 SUMMARY OF THE INVENTION

11 The invention provides a dental whitening composition whose viscosity is responsive to temperature changes, wherein the viscosity increases with an increase in temperature. These compositions also preferably have the ability to reverse their viscosity upon the lowering of temperature. The compositions of the invention comprise a whitening agent and a thermally responsive modifier.

12 Compositions of the invention work very well in the oral environment where temperature is generally higher than ambient or the pre-treatment temperature of a composition. This differential in temperature thickens the composition and thus provides a thickened, semi-solid or gel-like composition in the oral environment.

13 A preferred method of use of the invention comprises dispensing the composition into a dental tray that is subsequently placed into a user's mouth. Upon exposure of the composition to the oral temperature, the composition thickens to a semi-solid or gel-like state. Alternatively, the composition can be

dispensed into a pre-warmed tray such that the composition thickens upon its contact with the tray.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a graphic illustration of the viscosity versus temperature data as described in Example 3.

DETAILED DESCRIPTION:

1 DESCRIPTION OF THE INVENTION

2 This invention overcomes the shortcomings of previous dental whitening compositions that experience a decrease in viscosity due to the increase in temperature from the intraoral environment. This is accomplished by providing dental whitening compositions that exhibit an increase in viscosity in response to an increase in temperature. As a separate advantage, compositions and methods of the present invention provide easy delivery of tooth whitening compositions, especially with those compositions that are initially a low viscosity liquid at its pre-treatment temperature. These compositions can be dispensed from delivery devices that have small orifices, require less force to dispense and become thicker or more viscous only upon being exposed to the temperature of the oral environment.

3 Compositions of this invention are particularly suitable for use in the intraoral environment where a composition having a pre-treatment temperature at or lower than ambient (room temperature) is applied to a user's tooth surfaces that is near or at oral temperature of about 30.degree. C.-39.degree. C. For certain dental applications, it is preferred that the composition be thermally reversible. In that application, the composition not only has the ability to increase its viscosity at an elevated intra-oral temperature, but also reverses or decreases its viscosity upon a decrease in temperature.

4 The capacity of the dental composition to thicken at human body temperatures is a critical feature of the invention, for it is in this property that many of the disadvantages of previous approaches are overcome. The dissipative characteristic of liquid solutions is avoided since the compositions herein experience thickening at the site of treatment. Moreover, the problems of formulation, handling, delivery and application of viscous compositions are overcome since the present compositions may be free-flowing liquids prior to treatment.

5 A "semi-solid," as used herein, is a material whose physical state is between a liquid and solid state, pure or mixed solvent or solution entrained within a network, and can be alternatively be considered as a gel. By "pure or mixed solvent and/or solution," as stated herein, it is recognized that a mixture of solvents may be absorbed by the network. Additionally, the solvent may include salts or other additives so as to form a solution, which may also be absorbed or entrained within the network.

6 "Thickening" as used herein, is where a composition undergoes a substantial increase in the viscosity of the composition. The degree of thickening is dependent on the initial viscosity of the composition.

7 In a preferred embodiment of the invention, the initial viscosity of the composition may be low enough such that the composition is in a liquid state. Subsequently, upon exposure to a temperature of about near or at body temperature, the viscosity increases to result in a thickened composition. A viscosity increase in the range of about 10- to about 100-fold can be

experienced when the initial viscosity is low enough such that the composition is a liquid. Thus, for example, a composition in a liquid state may have a viscosity of about 0 to about 7000 poise. In response to an increase in temperature, the viscosity of the composition can increase to at least about 10,000 poise. Upon the lowering of the temperature, the composition preferably has the ability to reverse its viscosity and return to flow properties of a liquid.

8 Yet another preferred embodiment of the invention is when the initial viscosity of the composition is at a level at which the composition is in a semi-solid or gelatinous state at pre-treatment temperature, and upon exposure to a higher treatment temperature, the composition transforms into an "ultra-thick" or "ultra-gel" composition or one with a substantially higher viscosity and very low flow characteristics. These compositions typically have an initial viscosity of no less than about 7000 poise, which then thicken about 2- to about 5-fold.

9 The pre-treatment temperature is the temperature at which the composition is subjected to prior to application or treatment. The range for the pretreatment temperature can be about 5.degree. C. to about 29.degree. C., although there may be certain instances where the temperature may be outside this range. Having a pre-treatment temperature at about 2.degree. C. to 25.degree. C. allows the composition to be easily stored at ambient or room temperature. Alternatively, the compositions of the invention can also be advantageously stored at lower, refrigeration pre-treatment temperatures of about 5.degree. C. to about 10.degree. C. to provide improved stability and shelf life.

10 The treatment temperature is the temperature at which the composition is exposed to during intraoral application. This can be at or near body temperature, or about 30.degree. C. to about 39.degree. C.

11 In accordance with the invention, the dental composition consists of a water-miscible, physiologically compatible medium which is a liquid or gel at ambient temperature below about 30.degree. C. and experiences thickening at oral temperatures above about 30.degree. C. It has been found that a composition having a thickening transition temperature in the range of from about 25.degree. C. to about 40.degree. C. is useful in the practice of the present invention. Preferably, the thickening occurs in a temperature range of from about 25.degree. C. to about 39.degree. C., and more preferably from about 30.degree. to about 35.degree. C.

12 Compositions of this invention are comprised of a solvent, a whitening agent and a thermally responsive viscosity modifier that provides the desired viscosity increase at the desired elevated temperature range. Optionally, other adjuvants may be added to the composition. Preferably, the composition of this invention should be physiologically compatible so that no adverse reaction occurs if the tooth whitening composition comes in contact with human tissue or fluids. The solvent, whitening agent, and thermally responsive viscosity modifier may be contained in one mixture or contained separately in a multiple-part system. In a multiple-part system, the whitening agent may be kept physically separate from the viscosity modifier, to be admixed just prior to treatment.

13 As used herein, a "thermally responsive viscosity modifier" is one or more polymeric substances that provides the composition or polymeric system the capability of substantially increasing its viscosity in response to an increase in temperature. Suitable polymeric substances useful as thermally responsive viscosity modifiers include polyoxyalkylene polymers, particularly the polymeric surfactants available under the tradename PLURONIC. This class of polymers is available commercially from BASF Wyandotte Corporation. Other polyoxyalkylene polymers may also be useful as a thermally-responsive composition material.

14 A preferred dental composition in accordance with this invention comprises in

aqueous solution of a selected polyoxyethylene-polyoxypropylene block copolymer. A composition comprising polyoxyethylene-polyoxypropylene block copolymers in which the number of polyoxyethylene units is at least about 50% of the number of units in the total molecule, and the block copolymer having an average molecular weight of from about 1100 to about 15,500 has been found to be particularly useful. It is more preferable that a composition comprises about 70% polyoxyethylene units of the total number of monomeric units in the copolymer and the copolymer has an average molecular weight of about 11,500. PLURONIC F-127 is a material that meets these criteria.

15 The PLURONIC polymers are closely related block copolymer that may be generically classified as polyoxypropylene-polyoxyethylene condensates that terminate in primary hydroxyl groups. These polymers are formed by the condensation of propylene oxide into a propylene glycol nucleus followed by the condensation of ethylene oxide onto both ends of the polyoxypropylene base. The polyoxyethylene hydrophilic groups on the ends of the base pre-polymer are controlled in length to constitute from about 10% to about 80% by weight of the final polymer.

16 The PLURONIC polymer series of products may be represented empirically by the formula: HO(C.sub.2 H.sub.4 O).sub.a (C.sub.3 H.sub.6 O).sub.b(C.sub.2 H.sub.4 O).sub.c H where a and c are statistically equal.

17 The concentration of the block copolymers is an important parameter and can be formulated in such a manner corresponding to the other components' concentrations. By adjusting the concentration of the copolymer to accommodate other solutes present in the composition, any desired liquid to semi-solid transition temperature in the critical range of above ambient temperature and below body temperature can be achieved. Thus, the principal consideration is the selection of a concentration which, in conjunction with all of the constituents of the composition, will provide a liquid to semi-solid transition or alternatively, a gel to "ultra-gel" transition temperature in the required range.

18 It has been found that a useful block copolymer concentration is from about 5% to about 40% by weight (wt. %) of the composition, preferably from about 15 wt. % to about 26 wt. % of the.composition. Excellent results have been obtained using aqueous solutions having from about 17 wt. % to about 26 wt. % of PLURONIC F-127.

19 Another known system which is liquid at room temperature, but forms a semi-solid when warmed to about body temperature is formed from tetrafunctional block polymers of polyoxyethylene and polyoxypropylene condensed with ethylenediamine, commercially available under the tradename TETRONIC polymer (BASF Wyandotte Corp.). These compositions are formed from approximately 10% to 50% by weight of the polymer in an aqueous medium. See, for example, U.S. Pat. No. 5,252,318 which is incorporated by reference herein.

20 Particularly preferred polymers for compositions of the invention are the PLURONIC F-127 and F-108 and the class of TETRONIC polymers. These viscosity modifiers are block copolymers of ethylene oxide and propylene oxide. Thickening tendencies of block copolymers increase as ethylene oxide content and total molecular weight increase. Thermally responsive block copolymers have been disclosed in U.S. Pat. Nos. 4,474,751; 4,474,752; 5,441,732; and 5,252,318, as well as the Product Catalog, "BASF Performance Chemicals," all the teachings of which are incorporated by reference herein. These block copolymers offer extremely low toxicity and a high degree of mildness for applications involving human contact.

21 A preferred solvent for the composition of this invention is water. The concentration of water in the composition can be in the range of from about 30 wt. % to about 90 wt. % of the composition, and is preferably from about 50 wt. % to about 80 wt. %. More preferably, water can exist in the range of about 50 wt. % to about 75 wt. % of the composition. The water used in forming the

aqueous solution is preferably purified, as by distillation, filtration, ion-exchange or the like.

22 Other solvents may be used, including anhydrous solutions comprising a polyol component such as propylene glycol or polyethylene glycol. Propylene glycol may be present in the composition in an amount from about 10 wt. % to about 55 wt. % of the composition. Polyethylene glycol may be used in the practice of this invention, having a, molecular weight from about 400 to about 1500 and may be in an amount from about 10 wt. % to about 50 wt. % of the composition. Glycerin may also be used as a constituent of the composition.

23 The whitening agent used in the present invention may be any material that has the effect of whitening teeth. Whitening agents are preferably selected from hydrogen peroxide and its urea complex: carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2). These whitening agents are also known by alternative names, including, urea hydrogen peroxide, hydrogen peroxide carbamide, or perhydrol-urea. Alternatively, sodium hypochlorite may be suitable for use as the whitening agent. The concentration of a whitening agent in the composition can vary depending upon its reactivity. With carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 40%, with a range from about 4% to about 21% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

24 Other adjuvants can be added to the composition for certain purposes. For example, a preferred embodiment of the invention can contain fluoride, a desirable additive in oral compositions. Additives may also be included in the composition to promote the stability of the formulation. Anti-microbial agents, antifungal agents, and preservatives may be added to the composition to improve its shelf-life. Adhesive modifiers, which reduce or increase the stickiness of the composition may also be included in the formulation. The compositions may further include other adjuvants such as fillers, dyes, cariostatic agents, flavorings, sweeteners, medicaments and sodium bicarbonate.

25 Various methods can be employed in using the composition of this invention. One method of use of these whitening compositions entails application of the composition to the tooth structure directly from the composition's container or dispenser such as a bottle, syringe, or tube. Alternatively, the whitening composition can be applied by using a brush to paint it onto the tooth surface. The composition is kept on the user's tooth surface(s) for a desired time period to effectuate whitening. The length of time the composition is in contact with the tooth surface(s) would depend on the amount of discoloration the user prefers to remove.

26 In a preferred method, the whitening composition is loaded into a dental tray. Such dental trays can be custom fitted to a user's denition and be made with or without reservoirs. A preferred reservoir is described in U.S. patent application No. 53911USA1A, filed on Aug. 13, 1998, entitled Medication Delivery Tray, assigned to the assignee of the present invention, the disclosure of which is incorporated herein by reference. Dental trays can be made from varying thicknesses and softness of pliable thermo-formable plastic materials. Typically, these materials are 0.02-0.08 inches thick. After dispensing or loading the whitening composition into the dental tray, the user then places the loaded tray into the mouth and initiates thickening of the composition. The thickening occurs when the composition is exposed to the elevated treatment temperature of the oral environment. The tray is retained in the mouth to effectuate whitening of the tooth surface(s) for a sufficient period of time to remove discoloration.

27 An alternative method of use incorporates a pre-warmed dental tray into which the composition is loaded. Upon contact of the composition having a pre-treatment temperature, with the tray having a higher temperature, the composition experiences thickening. This method provides easy handling of a loaded tray into a user's mouth, with minimal fear of the composition moving to

an undesired section of the tray or having the composition flow out of the tray.

28 Where the compositions are thermally reversible, the composition can be readily removed from the denition or tray by cooling the material below the liquid to semi-solid transition temperature, thus reversing the thickening effect. This can be accomplished with cool water or other physiologically compatible liquid. Alternatively, the concentrations of the components in the whitening composition may be adjusted and diluted by adding water or other liquid solution in the oral cavity. By adjusting the concentrations of the components, the transition temperature is correspondingly adjusted, and thus provides the user the ability to remove the composition even with warm solutions. Water or other liquid solutions may be administered through a rinsing cup, squirt bottle, a liquid dispensing dental tool, or any other liquid dispensing device that can provide solution to the oral environment. Preferably, administrating of cool or cold water onto the composition can provide a significant decrease in viscosity. Alternatively, the composition may be brushed, wiped, or blown off.

29 These and other aspects of the invention are illustrated by the following examples which should not be viewed as limiting in scope. Unless otherwise indicated, all molecular weights are number average molecular weights and all ratios, parts and percentages are by weight.

30 EXAMPLES

31 Preparation of Stock Solution 1

32 An aqueous stock solution containing approximately 15% hydrogen peroxide(H.sub.2 O.sub.2) was prepared by transferring 5 grams of a 30% H.sub.2 O.sub.2 (J. T. Baker) and 5 grams of distilled water to a glass vial. The stock solution was mixed thoroughly.

33 Preparation of Stock Solution 2

34 An aqueous stock solution containing approximately 20% urea hydrogen peroxide (carbamide peroxide) was prepared by transferring 4 grams of 97% urea hydrogen hydrogen peroxide (Sigma) and 16 grams of distilled water to a glass vial. The stock solution was mixed thoroughly. (The hydrogen peroxide content of the urea hydrogen peroxide was about 35%). Stock solution contained about 7% H.sub.2 O.sub.2.

35 Example 1

36 A thermally-reversible hydrogen peroxide composition was prepared by transferring the ingredients below to a glass vial and mixing thoroughly until a colorless and transparent liquid solution was obtained.

Stock Solution 1	1.60 grams
PLURONIC F127 (BASF)	0.40 grams
	2.00 grams

37 The above solution contained approximately 12% hydrogen peroxide, 68% water and 20% PLURONIC F127. The glass vial containing the liquid peroxide solution was warmed to body temperature by holding the vial in a human hand. Following about one to two minutes, the liquid was transformed into a colorless, transparent composition that did not flow upon inverting the vial. The vial was allowed to

cool to room temperature wherein the composition was transformed back to the low viscosity state. This cycle was repeated; several times with the same outcome.

38 The liquid and semi-solid (gel) states were both semi-quantitatively evaluated for hydrogen peroxide utilizing hydrogen peroxide analysis strips. The analysis utilized "EM Quant Peroxide Test Strips" (EM Science Gibbstown, N.J., Catalog No. 10011-1). The compositions were evaluated according to the manufacturer's directions.

39 Results of the tests indicated that both the liquid and semi-solid states contained significant amounts of available peroxide.

40 The same sample was re-evaluated 2 months later and found to still exhibit thermally-reversible characteristics and comparable hydrogen peroxide levels based oil the semi-quantitative analysis.

41 Example 2

42 A thermally reversible composition containing urea hydrogen peroxide was prepared by transferring the ingredients below to a glass vial and mixing thoroughly until a colorless and transparent liquid solution was obtained.

Stock Solution 2	4.00 grams
PLURONIC F127 (BASF)	1.00 grams
	5.00 grams

43 The above solution contained approximately 16% urea hydrogen peroxide (or about 5.6% hydrogen peroxide), 64% water and 20% PLURONIC F127. The glass vial containing the liquid peroxide solution was warmed to body temperature by holding the vial in a human hand. After about 1 minute, the liquid transformed to a colorless, transparent composition that did not flow upon inverting the vial. The vial was allowed to cool to room temperature wherein the semi-solid composition was transformed back to the low viscosity state. This cycle was repeated several time with the same outcome.

44 The liquid and semi-solid states were both semi-quantitatively evaluated or hydrogen peroxide utilizing hydrogen peroxide analysis strips, EM Quant Peroxide Test Strips (EM Science; Gibbstown, N.J., Catalog No. 10011-1), according to the manufacturer's directions. Both the liquid and semi-solid states indicated the presence of significant amounts of available peroxide.

45 The same sample was re-evaluated 9 days later and found to still exhibit thermally-reversible characteristics and comparable hydrogen peroxide levels based on the semi-quantitative analysis.

46 Table 1 summarizes the results of the two previous examples. The "+" indicates a increase in the viscosity. The "-" indicates a decrease in the viscosity. The presence of hydrogen peroxide as indicated in the table are the results obtained from the semi-quantitative test using the EM Quant Peroxide Test Strips and test method.

TABLE 1

	35.degree. C.	25.degree. C.

	% Peroxide	35.degree. C. viscosity	25.degree. C. viscosity	H.sub.2 O.sub.2 Present			
H.sub.2 O.sub.2 Present		viscosity @ 9 days		viscosity @ 9 days		Present @ 9 days	
Example 1	12	+	+	-	-	Yes	Yes
Example 2	16	+	+	-	-	Yes	Yes

47 Example 3

48 Several compositions that have been evaluated for viscosity as a function of temperature. The compositions are described below:

TABLE 2

Comparative Sample A

Component	parts by weight (g)	% by weight	Physical Appearance at 23.degree. C.	Physical Appearance at body temp
Urea hydrogen peroxide	20	20	Low viscosity, colorless liquid	Low viscosity, Colorless liquid
Water	80	80		

TABLE 3

Sample B

Component	Parts by weight (g)	% by weight	Physical Appearance at 23.degree. C.	Physical Appearance at Body temp
Urea hydrogen	20	16	Low viscosity, Colorless liquid	non-flowing, colorless gel
Water	80	64		
PLURONIC	25	20		

F-127

TABLE 3

Sample B

Component	Parts by weight (g)	% by weight	Physical Appearance at 23.degree. C.	Physical Appearance at Body temp
Urea hydrogen	20	16	Low viscosity, Colorless liquid	non-flowing, colorless gel
Water	80	64		
PLURONIC F-127	25	20		

49 Samples were further evaluated for viscosity as a function of temperature between 15.degree. C. and 45.degree. C. utilizing a Rheometrics RDA II Rheometer. Complex viscosity, .eta.* (units of measure is in Poise), versus temperature data were obtained using a controlled strain rheometer ("RDA2", Rheometrics Scientific, Piscataway, N.J.). A parallel plate geometry was used with a plate diameter of 25 mm and a gap of approximately 1 mm. Samples were subjected to an oscillatory strain of 10% applied at a frequency of 1 rad/sec while the temperature was ramped from 15.degree. C. and 45.degree. C. (3.degree. C./ min).

50 Set out below is the RDA viscosity data. FIG. 1 illustrates that aqueous compositions containing PLURONIC F127 polymer exhibit a relatively sharp increase in viscosity upon warming from room temperature to about 45.degree. C. Sample C which exhibited semi-solid-like characteristics at room temperature (due to the incorporation of a filmed silica) also increased substantially upon an increase in temperature.

TABLE 5

A		B		C	
Temp .degree. C.	.eta.* P	Temp .degree. C.	.eta.* P	Temp .degree. C.	.eta.* P
14.02	9.75424	17.88	2308.56	18.5	52951.5
14.28	3.35258	17.88	2379.72	18.3	42757.9
15.36	7.33292	18.54	2587.46	18.79	41559.9
17.28	3.46242	19.42	3111.41	19.64	41144.7
19.46	5.85152	20.91	3711.59	20.76	41347.4

21.12	5.79953	22.36	4580.71	22.09	42047
22.89	7.09599	23.72	5661.42	23.51	43615.7
24.91	4.19887	25.46	7221.65	24.04	45494.3
26.31	0.87001	26.85	8940.38	26.03	48768.7
28.23	3.13629	28.73	25375.6	27.94	55250.6
30.12	4.57411	30.7	29698.2	29.57	82062.6
31.6	4.7215	32.07	33651.8	31.31	94988.5
33.2	9.01765	33.57	37181.2	32.83	1.04E+05
35.02	8.0025	35.22	40557.8	34.36	1.09E+05
36.75	2.94618	36.89	43766.3	36.09	1.13E+05
38.44	4.24626	38.43	46677.4	37.49	1.20E+05
40.85	1.08273	40.01	49322.7	38.95	1.26E+05
42.92	5.04081	41.84	52296.6	40.7	1.32E+05
		43.52	54490.4	42.2	1.36E+05
				43.9	1.39E+05

CLAIMS:

We claim:

1. A method of whitening teeth in the oral environment using a dental composition comprising a tooth whitening agent and about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier, wherein the composition is in a low viscosity liquid state at a pre-treatment temperature and a highly viscous state at a treatment temperature that is higher than the pre-treatment temperature, comprising:

applying the composition through an orifice of a syringe onto a tooth surface, wherein the composition is at the pretreatment temperature and in the low viscosity liquid state prior to being applied onto the tooth surface,

allowing the composition to warm to the treatment temperature and increase in viscosity to the highly viscous state wherein the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pre-treatment temperature, and

allowing the composition to remain on the tooth surface for a sufficient time to effectuate whitening, whereby said high viscosity dental whitening composition if pre-gelled or pre-thickened being difficult to extrude through a small orifice, said free flowing low viscosity liquid dental whitening composition being readily deliverable through a syringe to target sites on the tooth surface intended to be whitened where it thickens and forms an immobile gel on the target site which is at or near about 30.degree. C. to about 39.degree. C. where it is kept for the desired period of time to effect whitening, said composition being readily removable from the tooth surface by cooling the material below the liquid to semi-solid transition temperature, and thereby reversing the thickening effect.

2. The method of claim 1 wherein the pre-treatment temperature is room temperature.

3. The method of claim 1 wherein the treatment temperature is body temperature.

4. The method of claim 1 wherein the thermally responsive viscosity modifier is a polyoxyalkylene polymer.

5. The method of claim 1 wherein the whitening agent is selected from the group consisting of hydrogen peroxide, carbamide peroxide, sodium hypochlorite, and mixtures thereof.

6. The method of claim 1 wherein the composition further comprises a solvent.

7. The method of claim 6 wherein the solvent comprises water.

8. The method of claim 1 wherein the visosity of the composition at the treatment temperature is about 10 times to about 100 times the viscosity of the composition at the pre-treatment temperature.

9. The method of claim 1 wherein the composition decreases in viscosity upon cooling from the treatment temperature.

10. The method of claim 9 further comprising removing the composition from the tooth surface by cooling the composition from the treatment temperature.

11. The method of claim 10 wherein the composition is cooled by application of a cool liquid.

12. The method of claim 11 wherein the liquid comprises water.

13. A method of whitening teeth in the oral environment using a dental composition comprising a tooth whitening agent and about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier, wherein the composition is in a low viscosity semi-solid state at a pre-treatment temperature and a highly viscous state at a treatment temperature that is higher than the pre-treatment temperature, comprising:

applying the composition through an orifice of a syringe onto a surface, wherein the composition is at the pretreatment temperature and in the low viscosity semi-solid state prior to being applied onto the surface,

allowing the composition to warm to the treatment temperature and increase in viscosity to the highly viscous state wherein the viscosity of the composition at the treatment temperature is at least about 2 times the viscosity of the composition at the pre-treatment temperature, and

allowing the composition to remain on the tooth surface for a sufficient time to effectuate whitening, whereby said high viscosity dental whitening composition if pre-gelled or pre-thickened being difficult to extrude through a small orifice, said free flowing low viscosity semi-solid dental whitening composition being readily deliverable through a syringe to target sites on the the surface intended to be whitened where it thickens and forms an immobile gel on the target site which is at or near about 30.degree. C. to about 39.degree. C. where it is kept for the desired period of time to effect whitening, said composition being readily removable from the tooth surface by cooling the material below the low viscosity semi-solid to highly viscous solid transition temperature, and thereby reversing the thickening effect.

14. The method of claim 13 wherein the pre-treatment temperature is room temperature.

15. The method of claim 13 wherein the treatment temperature is body temperature.

16. The method of claim 13 wherein the viscosity of the composition at the treatment temperature is about 2 times to about 5 times the viscosity of the composition at the pre-treatment temperature.

17. The method of claim 13 wherein applying the composition onto a surface comprises applying the composition onto a tooth surface.

18. A method of whitening teeth in the oral environment using a dental composition comprising a tooth whitening agent and about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier, wherein the composition is in a low viscosity semi-solid state at a pre-treatment temperature and a highly viscous state at a treatment temperature that is higher than the pre-treatment temperature, comprising:

applying the composition through an orifice of a syringe onto a surface, wherein the composition is at the pretreatment temperature and in the low viscosity semi-solid state prior to being applied onto the surface,

allowing the composition to warm to the treatment temperature and increase in viscosity to the highly viscous state wherein the viscosity of the composition at the treatment temperature is at least about 10 times the viscosity of the composition at the pre-treatment temperature, and

allowing the composition to remain on the surface for a sufficient time to effectuate whitening.

19. The method of claim 18 wherein applying the composition onto a surface comprises applying the composition onto a tooth surface.

20. The method of claim 18 wherein applying the composition through an orifice comprises applying the composition through an orifice of a syringe.

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L11: Entry 1 of 2 File: USPT Jun 23, 1998

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TITLE: Methods for treating teeth with anticariogenic and antimicrobial dental compositions

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Salt Lake City	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

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PARENT-CASE:
This application is a file wrapper continuation of U.S. patent application Ser. No. 08/099,247, filed Jul. 28, 1993, in the name of Dan E. Fischer, D. D. S. for "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES", now abandoned, which is a file wrapper continuation of U.S. patent application Ser. No. 07/985,700, filed Dec. 2, 1992, in the name of Dan E. Fischer, D. D. S. for "SUSTAINED RELEASE DENTAL COMPOSITIONS AND METHODS FOR TREATING TEETH SURFACES", now abandoned, which is a file wrapper continuation of U.S. patent application Ser. No. 07/718,210, filed Jun. 20, 1991, now abandoned, which is a divisional of U.S. patent application Ser. No. 07/497,934, filed Mar. 22, 1990, now abandoned.

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PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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Trial Testimony of Roger Hicks (Rebuttal), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Bryan D. Tarr (Direct), Civil Action No. 2:95CV 0163W (D. Utah).
Trial Testimony of Garold S. Yost (Rebuttal), Civil Action No. 2:95CV 0163W (D. Utah).
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ART-UNIT: 152

PRIMARY-EXAMINER: Bawa; Raj

ABSTRACT:

The present invention discloses sustained release dental compositions, such as tooth bleaching or fluoride-containing compositions, having high viscosity and stickiness for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent to the tooth surfaces being treated is preferably used in conjunction with the sustained release dental compositions. The sustained release dental compositions include carboxypolymethylene in a concentration in a range from about 3.5% to about 12% by weight of the dental composition, as well as a base so that the pH of the dental composition is in a range from about 5 to about 7, which results in a very high viscosity composition.

The carboxypolymethylene also inhibits dilution of the dental compositions by saliva so that the compositions stay within the tray reservoirs over time, thereby providing sustained release, or prolonged delivery, of the active dental agent. The carboxypolymethylene adds a unique tackiness to the dental composition that helps to retain and seal the soft tray material against the patient's teeth.

18 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Prior Art

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4) instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (c) expectorate any excess bleaching solution, (d) change the bleaching solution every 1 to 2.5 hours, and (e) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patients. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix

material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them; gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the

dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental composition will be maintained over a greater period of time in a high salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycols or other polyols.

14 It is currently preferred that the amount of water in the sustained release

dental composition be in the range from about 10% to about 60% by weight, and preferably in the range from about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use of concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention; gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 11/4 mm to about 11/2 mm from gingival line 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by

expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patients will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patients suspected of being breixers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agents within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase in effectiveness has also been observed when using existing bleaching agents with trays incorporating reservoirs compared to conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the

treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition, such as a composition that includes one or more fluoride salts and/or complexes, may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2	gm	10%
Water	27.5	gm	21%
Glycerine	74.6	gm	57%
Carbopol 934P	9.5	gm	7%
Sodium hydroxide (50%)	6.5	gm	5%

37 The Carbopol 934P was obtained from B. F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced in a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent

examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent
Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of Example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained at about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal

pockets such as tetracycline may be, incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated that the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by united states letters patent is:

1. A method for providing anticariogenic treatment of a patient's teeth consisting essentially of the following steps:

(a) obtaining a dental tray configured to cover a patient's teeth to be treated and configured to hold an anticariogenic dental composition therewithin;

(b) placing within said dental tray an anticariogenic dental composition having sufficient stickiness to retain said dental tray over the patient's teeth, the dental composition consisting essentially of:

(i) an anticariogenic agent for treating teeth in contact with the anticariogenic agent, the anticariogenic agent selected from the group consisting of fluoride salts, complexes, and mixtures thereof;

(ii) a matrix into which the anticariogenic agent is dispersed, the matrix containing therein dispersed carboxypolymethylene that has been neutralized

with a base in a range from about 3.5% to about 12% by weight of the anticariogenic dental composition;

(iii) water in a range from about 10% to about 60% by weight of the dental composition; and

(iv) a base to adjust the pH of the dental composition to within a range from about 5 to about 7;

(c) positioning the dental tray over the patient's teeth so that the anticariogenic dental composition is in contact with the patient's teeth;

(d) allowing the dental tray to remain positioned over the patient's teeth for at least about two hours; and

(e) removing the dental tray from the patient's teeth.

2. A method for providing anticariogenic treatment of a patient's teeth as defined in claim 1, wherein the anticariogenic agent comprises sodium fluoride in a range from about 1% to about 5% by weight of the dental composition.

3. A method for providing anticariogenic treatment of a patient's teeth as defined in claim 1, wherein the carboxypolymethylene comprises a carboxypolymethylene resin having an approximate molecular weight of about 3.times.10.sup.6.

4. A method for providing anticariogenic treatment of a patient's teeth as defined in claim 1, wherein the matrix includes carboxypolymethylene in a range from about 4.5% to about 10% by weight of the anticariogenic dental composition.

5. A method for providing anticariogenic treatment of a patient's teeth as defined in claim 1, wherein the matrix includes carboxypolymethylene in a range from about 6% to about 8% by weight of the anticariogenic dental composition.

6. A method for providing anticariogenic treatment of a patient's teeth as defined in claim 1, wherein the matrix includes glycerin.

7. A method for providing antimicrobial treatment of a patient's teeth consisting essentially of the following steps:

(a) obtaining a dental tray configured to cover a patient's teeth to be treated and configured to hold an antimicrobial dental composition therewithin;

(b) placing within said dental tray an antimicrobial dental composition having sufficient stickiness to retain the dental tray over the patient's teeth, the dental composition consisting essentially of:

(i) an antimicrobial agent for treating teeth in contact with the antimicrobial agent;

(ii) a matrix into which the antimicrobial agent is dispersed, the matrix containing dispersed therein carboxypolymethylene that has been neutralized with a base in a range from about 3.5% to about 12% by weight of the antimicrobial dental composition;

(iii) water in a range from about 10% to about 60% by weight of the antimicrobial dental composition; and

(iv) a base to adjust the pH of the dental composition to within a range from about 5 to about 7;

(c) positioning the dental tray over the patient's teeth so that the antimicrobial dental composition is in contact with the patient's teeth;

(d) allowing the dental tray to remain positioned over the patient's teeth for at least about two hours; and

(e) removing the dental tray from the patient's teeth.

8. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the antimicrobial dental agent comprises chlorhexidine gluconate.

9. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the antimicrobial dental agent comprises tetracycline.

10. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the carboxypolymethylene comprises a carboxypolymethylene resin having an approximate molecular weight of about 3.times.10.sup.6.

11. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the matrix includes carboxypolymethylene in a range from about 4.5% to about 10% by weight of the antimicrobial dental composition.

12. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the matrix includes carboxypolymethylene in a range from about 6% to about 8% by weight of the antimicrobial dental composition.

13. A method for providing antimicrobial treatment of a patient's teeth as defined in claim 7, wherein the matrix includes glycerin.

14. A method for providing anticariogenic or antimicrobial treatment of a patient's teeth, the method consisting essentially of the following steps:

(a) obtaining a dental tray configured to cover a patient's teeth to be treated and configured to hold an anticariogenic or antimicrobial dental composition therewith;

(b) placing within said dental tray an anticariogenic or antimicrobial dental composition having sufficient stickiness to retain the dental tray over the patient's teeth, the dental composition formed by mixing together the following components;

(i) a dental agent for treating teeth in contact with the dental agent, the dental agent selected from the group consisting of fluoride compositions, chlorhexidine gluconate, tetracycline, and mixtures of the foregoing;

(ii) a matrix that contains dispersed therein carboxypolymethylene in a range from about 3.5% to about 12% by weight of the anticariogenic dental composition;

(iii) water in a range from about 10% to about 60% by weight of the dental composition; and

(iv) a base to adjust the pH of the dental composition to within a range from about 5 to about 7;

(c) positioning the dental tray over the patient's teeth so that the anticariogenic or antimicrobial dental composition is in contact with the patient's teeth;

(d) allowing the dental tray to remain positioned over the patient's teeth for at least two hours; and

(e) removing the dental tray from the patient's teeth.

15. A method for providing anticariogenic or antimicrobial treatment of a patient's teeth as defined in claim 14, when the matrix further includes glycerin.

16. A method for providing anticariogenic or antimicrobial treatment of a patient's teeth as defined in claim 14, wherein the carboxypolymethylene is in a range from about 4.5% to about 10% by weight of the dental composition.

17. A method for providing anticariogenic or antimicrobial treatment of a patient's teeth as defined in claim 14, wherein the carboxypolymethylene is in a range from about 6% to about 8% by weight of the dental composition.

18. A method for providing anticariogenic or antimicrobial treatment of a patient's teeth as defined in claim 14, wherein the dental composition further includes a peroxide compound.

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L11: Entry 2 of 2 File: USPT Jun 23, 1998

US-PAT-NO: 5770105
DOCUMENT-IDENTIFIER: US 5770105 A

TITLE: Methods for manufacturing sticky bleaching compositions

DATE-ISSUED: June 23, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

APPL-NO: 08/ 722397 [PALM]
DATE FILED: September 30, 1996

PARENT-CASE:
RELATED APPLICATIONS This application is a division of copending application Ser. No. 08/378,315 filed Jan. 25, 1995 pending in the name of Dan E. Fischer, D.D.S., "ANTICARIOGENIC AND ANTIMICROBIAL DENTAL COMPOSTIONS AND METHODS FOR TREATING TEETH SURFACE", which is a file wrapper continuation of copending application Ser. No. 08/099,247 filed Jul. 28, 1993 for "SUSTAINED RELEASE DENTAL COMPOSTIONS AND METHODS FOR TREATING TEETH SURFACES" (abandoned), which is a file wrapper continuation of copending application Ser. No. 07/985,700 filed Dec. 2, 1992 (abandoned), which is a file wrapper continuation of copending U.S. application Ser. No 07/718,210 filed Jun. 20, 1991 (abandoned), which is a divisional of U.S. application Ser. No. 07/497,934, filed Mar. 22, 1990 (abandoned).

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PRIOR-ART-DISCLOSED:

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ART-UNIT: 128

PRIMARY-EXAMINER: Anthony; Joseph D.

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

17 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

BRIEF SUMMARY:

1 BACKGROUND

2 1. The Field of the Invention

3 The present invention relates to sustained release dental compositions and methods for treating teeth surfaces. More particularly, the present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching compositions, used in combination with a dental tray having reservoirs for holding the dental composition located adjacent the teeth surfaces to be treated.

4 2. The Relevant Technology

5 Virtually all people desire white or whiter teeth. To achieve this goal, people either have veneers placed over their teeth or have their teeth chemically bleached. In the past, patients who desired to have their teeth bleached had to submit to conventional in-office bleaching techniques. This usually involved carefully placing a hydrogen peroxide solution (typically 30% H.sub.2 O.sub.2) on the teeth, protecting the sensitive soft tissues with a ligated rubber dam, and applying heat or light to the solution. Such treatments typically last 30 minutes to 1 hour with from 4 to 10 appointments being necessary for a significant change. Only the labial surface of the 6-8 front teeth is treated.

6 Since its introduction in early 1989, there has been a growing interest among the dental profession in home-use tooth bleaching products and methods. A current representative technique includes: (1) making an alginate impression of the patient's teeth; (2) making a stone cast of the impression; (3) vacuum forming a tray from the cast, usually from thin (0.020-0.030 inch) hard transparent material, and trimming to exclude gingival coverage; (4)

instructing the patient to (a) place 2-3 drops of a bleaching solution into each area of each tooth to be bleached, (b) place the tray in the mouth, (c) expectorate any excess bleaching solution, (d) change the bleaching solution every 1 to 2.5 hours, and (e) remove the tray during meals. A few recommend wearing the tray during the night.

7 The most commonly used dental bleaching agent is 10% carbamide peroxide (CO(NH.sub.2).sub.2 H.sub.2 O.sub.2), also called urea hydrogen peroxide, hydrogen peroxide carbamide, and perhydrol-urea. Carbamide peroxide has been used by dental clinicians since the 1960's as an oral antiseptic. Tooth bleaching was a side effect of extended contact time. Over the counter ("OTC") compositions of 10% carbamide peroxide are available as "Gly-Oxide" by Marion Laboratories and "Proxigel" by Reed and Carnrick.

8 Positive results using the foregoing technique have been reported. The effectiveness depends upon such factors as type and intensity of stain, bleaching agent contact time on teeth, and amount of available active ingredient in the bleaching agent. Because the time commitment for the actual bleaching process takes place outside the dental office, the cost for the procedure is substantially less than conventional in-office bleaching techniques. Moreover, patient discomfort associated with home-use tooth bleaching techniques both during and after treatment is reportedly less than that associated with conventional in-office bleaching.

9 Notwithstanding the foregoing advantages, there remain some important disadvantages to home-use bleaching products and techniques. One important disadvantage is that the bleaching agent must be frequently replaced during the day. Clinical test results indicate that saliva dilution and swallowing of the bleaching agent caused the volume of agent in the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching. Test results show that after one hour, less than one-half the original volume of bleaching agent was present. Thus, existing bleaching agents should be replenished about every hour in order to be effective.

10 Many patient's daytime schedules do not permit them to constantly replenish the bleaching agent. In addition, even the suggestion of periodically replenishing the bleaching agent during the night would not be favorably received by most patients. Because of the inconvenience of constantly replacing the dental agent, patient compliance is difficult to maintain, and since patient compliance determines the ultimate success of the treatment, the need to constantly replace the dental bleaching agent is a major inconvenience which limits the success of the treatment.

11 Another disadvantage with current home-use bleaching compositions and techniques is that it often takes weeks to see an observable result. Although some have reported lightening of teeth in shorter periods of time, in most cases the home-use bleaching treatment lasts from 4 to 6 weeks. Under such circumstances, patients often lose their enthusiasm for the procedure and often stop complying with the treatment regimen.

12 From the foregoing, it will be appreciated that what is needed in the art are improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

13 Additionally, it would be a significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

14 It would be another significant advancement in the art to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

15 It would be an additional advancement in the art to provide sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

16 Such sustained release dental compositions and methods for treating tooth surfaces are disclosed and claimed herein.

17 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

18 The present invention is directed to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

19 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to about 20%, with a range from about 4% to about 15% being most preferred.

20 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the dental bleaching agent. One currently preferred high viscosity matrix material is a supersaturated carboxypolymethylene composition. A quantity of base is preferably added to the carboxypolymethylene composition to adjust the pH to within about 5.0 to about 7.0.

21 The sustained release bleaching agents within the scope of the present invention have such a high viscosity that positive pressure is needed to dispense them, gravity is not sufficient. Unlike existing low-viscosity bleaching agents, the sustained release bleaching agents cannot be dispensed drop-wise from a bottle. A syringe, squeezable tube, or other similar positive pressure dispensing device must be used to dispense the bleaching compositions within the scope of the present invention.

22 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. The reservoirs are prepared by building a layer of rigid material on the stone cast on specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified cast using conventional techniques. Once formed, the tray is preferably trimmed barely shy of the gingival margin on both buccal and lingual surfaces. The resulting tray provides a perfect fit of the patient's teeth with reservoirs or spaces located where the rigid material was placed on the stone cast.

23 The reservoirs may also be creatively built into trays to provide additional bleaching agent to specific teeth or teeth surfaces which need more whitening than others. It has also been found that patients may experience less tooth discomfort from tray pressures when using a tray with built in reservoirs.

24 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean and that there be no restorations with leaky margins or exposed dentin. If there are large areas of exposed dentin or if restorations are inadequate, patients can develop mild to moderately severe pain.

25 The amount of whitening obtained during tooth bleaching is dependent upon (1) the length of time each day the tray is worn; (2) the number of days the tray

is worn; and (3) the susceptibility of the teeth to the bleaching agent. For maximum whitening, an accelerated treatment time of approximately 18-20 hours per day is recommended. The treatment schedule may be tailored to each patient's lifestyle or response to the treatment, but will usually include at least treatment during the patient's sleep. It has been found that treatment during sleep is the most productive single treatment time of the day since less mouth activity "pumps" material from the tray.

26 It is, therefore, an object of the present invention to provide improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

27 Another important object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced.

28 Yet another significant object of the present invention is to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth thereby providing noticeable lightening of a patient's teeth in a matter of days rather than weeks.

29 A further important object of the present invention is to provide an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

30 These and other objects and features of the present invention will become more fully apparent from the description which follows, or may be learned by the practice of the invention.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a stone cast of a patient's teeth with a rigid coating being applied to selected teeth surfaces.

FIG. 2 is a perspective view of the stone cast of FIG. 1 with a dental tray formed from the cast and trimmed according to the teachings of the present invention.

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 2.

FIG. 4 is a cross-sectional view taken along line 4--4 of FIG. 2.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 As summarized above, the present invention is generally related to high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition.

3 One currently preferred sustained release dental composition includes a dental bleaching agent, such as carbamide peroxide. The concentration of dental bleaching agent may vary depending upon its reactivity. For carbamide peroxide, for example, the currently preferred concentration range is from about 3% to

about 20%, with a range from about 4% to about 15% being most preferred. In the case of hydrogen peroxide, which is more reactive than carbamide peroxide, the currently preferred concentration range is from about 2% to about 10%.

4 The dental bleaching agent is preferably included in a high viscosity matrix material to form the sustained release dental composition. Suitable matrix materials that are preferably safe for oral use, do not readily dissolve in saliva, and do not react with or inactivate the dental bleaching agent. One currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F. Goodrich Company under the tradename "carbopol".

5 The normal concentration of various carboxypolymethylene resins in water, according to the manufacturer, is below about 2%. However, it has been found that by preparing supersaturated carboxypolymethylene compositions having an absolute concentration in the range from about 3.5% to about 12%, preferably from 4.5% to about 10%, suitable high viscosity, sustained release dental compositions may be prepared.

6 Due to the large quantities of non-aqueous components in the dental compositions within the scope of the present invention, the actual concentration of carboxypolymethylene in the total quantity of water in the dental composition will preferably be in the range from about 15% to about 35%, and most preferably from about 20% to about 30%. In some special applications where very high concentrations of carboxypolymethylene are desired, the concentration of carboxypolymethylene in the total quantity of water in the dental composition may even be as great as about 40%.

7 One currently preferred carboxypolymethylene composition is known as Carbopol 934P. Carbopol 934P is a high purity pharmaceutical grade of Carbopol 934, having an approximate molecular weight of about 3,000,000. In addition to thickening, suspending, and emulsifying, Carbopol 934P has been used in dry tablets to impart sustained release properties. Extensive toxicity studies have been conducted on Carbopol 934P, and a master file has been established with the Food and Drug Administration. It is listed as Carbomer 934P in the National Formulary.

8 It is believed other carboxypolymethylene resins, such as Carbopol 940, may be substituted for the Carbopol 934P. However, based upon clinical and laboratory evaluations, it has been found that Carbopol 940 dilutes faster than Carbopol 934P. In addition, Carbopol 934P is currently preferred because it is obtainable in a pharmaceutical grade. Therefore, Carbopol 934P is a currently preferred carboxypolymethylene composition.

9 The concentrated carboxypolymethylene compositions within the scope of the present invention have a number of important characteristics in addition to high viscosity. Enough carboxypolymethylene is added to the dental compositions beyond that required to provide high viscosity such that a significant quantity of saliva or water is required to lower the viscosity to the point that the dental agent may be diluted and washed out by saliva. Because the high level of carboxypolymethylene makes dilution from saliva difficult and more time consuming, the resulting dental compositions provide a sustained release of the dental agent.

10 In most cases, high levels of carboxypolymethylene will be preferred so that the sustained release action of the dental compositions will be maintained over a greater period of time in a highly salivating patient. However, in some cases it may be desireable to use lower concentrations of carboxypolymethylene so that the sustained release action will last a shorter period of time. Thus, by varying the concentration of carboxypolymethylene, some control over the period of dental agent activity may be obtained.

11 The concentrated carboxypolymethylene composition also has a unique tackiness or stickiness which retains and seals the thin soft tray material against the teeth thereby preventing migration of the composition out of the tray. The tackiness of the composition also keeps the composition within the reservoirs. It has been found that if too much carboxypolymethylene is used, the tackiness decreases and the composition encumbers complete tray insertion.

12 In order to obtain a concentrated carboxypolymethylene composition, it is recommended that the carboxypolymethylene be mixed with a quantity of glycerine before attempting to disperse it in water. The glycerine appears to enable the large quantities of carboxypolymethylene to be dispersed in water. It has also been observed that once the carboxypolymethylene and glycerine are mixed, it is important to quickly disperse the mixture in the water or else it becomes an unmanageable solid. It is recommended that the concentration of glycerine in the final sustained release dental composition be in the range from about 20% to about 70% by weight, and preferably in the range from about 30% to about 60% by weight.

13 In addition to functioning as a humectant, the glycerine also provides some flavor enhancement such that a bland flavor is perceived. A few possible substitutes for glycerine include polypropylene, sorbitol, some polyethylene glycol or other polyols.

14 It is currently preferred that the amount of water in the sustained release dental composition be in the range from about 10% to about 60% by weight, and preferably in the range from about 15% to about 40% by weight. It will be appreciated that the quantity of water in the total dental composition may come from different sources. For instance, the dental bleaching agent and base, discussed below, may come as aqueous solutions.

15 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition. It appears, based upon clinical and in vitro testing, that dental compositions with a pH below about 5 are able to etch enamel. To avoid etching enamel, it is currently preferred to have the pH of the sustained release bleaching composition in the range from about 5 to about 7. This is most easily accomplished by adding a base to the composition to adjust the pH. Inorganic and organic bases may be used, with the use of concentrated sodium hydroxide (50% NaOH) being one currently preferred embodiment. Although it is possible to use lower concentrations of sodium hydroxide or other bases, such as triethanolamine, there is a risk that the lower concentrations may dilute the dental composition and affect its viscosity or sustained release characteristics.

16 An important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep. That is, the sticky, high viscosity dental composition is still observable in the dental tray after an extended period of time, such as at the end of the night.

17 Unlike existing low-viscosity bleaching agents which are placed drop-by-drop into the tray, the sustained release bleaching agents within the scope of the present invention have such a high viscosity that they cannot be dispensed drop-wise into the tray from a bottle. Positive pressure is needed to expel the sustained release bleaching agents of the present invention, gravity is not sufficient.

18 One currently preferred method of dispensing the bleaching agent uses a syringe. Squeezable tubes and other similar dispensing devices may also be used to dispense the bleaching agent. Upon dispensing, the sustained release bleaching agent is sufficiently viscous that it does not settle or spread when dispensed, but remains as a single extruded strand of bleaching agent.

19 It is currently preferred to provide a unit dose of the dental agent in a

syringe or similar dispensing device. In this way, the patient can load the precise amount of dental agent onto the dental tray for each treatment period. By using such dispensing devices, the dentist is also able to monitor how many doses the patient has received and used.

20 An improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The general process for preparing dental trays is known in the art. For example, an alginate impression which registers all teeth surfaces plus gingival margin is made and a stone cast is promptly made of the impression. Excess stone is trimmed away for ease of manipulation and forming of the plastic tray.

21 Reference is now made to FIGS. 1-4. The present invention modifies known procedure by applying a thin coating 10 of rigid material to stone cast 12 over the teeth surfaces to be treated. As shown in FIG. 1, coating 10 may be conveniently applied using a brush tipped applicator 14. The coating may be also light cured for convenience. Care is taken to ensure that coating 10 is kept a distance greater than about 1 mm from gingival line 16 and preferably kept from about 1 1/4 mm to about 1 1/2 mm from gingival line or margin 16. The finished coating is preferably about 1/2 mm thick. It is particularly important when applying the rigid coating material to not cover over incisal edges 18 and occlusal edges 20. These edges should contact the finished tray to prevent vertical movement of the tray during use which could act as a pump by expressing out the bleaching agent and sucking in saliva.

22 A dental tray 22 is then vacuum formed from the modified cast using conventional techniques. Tray 22 is preferably constructed of soft transparent vinyl material having a preformed thickness from about 0.04 inch to about 0.06 inch. Soft material is more comfortable for the patient to wear. Most patient's will find 0.04 inch to be suitable. It will be appreciated that the final tray thickness may vary depending on the technique used to prepare the tray. Patient suspected of being bruxers or hard biters may require either a thicker or a harder material. Of course, patients should be counselled to not eat with trays in place or to bite firmly into them. In extreme cases, a thicker or harder plastic may be necessary.

23 Once formed, tray 22 is preferably trimmed barely shy of gingival margin 16 on both buccal and lingual surfaces. Enough tray material should be left to assure that all of the tooth will be covered to within about 1/4 mm to about 1/3 mm of the gingival border upon finishing and beveling of the tray periphery. It is also important to scallop up and around interdental papilla so that the finished tray does not cover them. All tray edges are preferably smoothed so that the lip and tongue will not feel an edge prominence. Slight adjustments to the tray may be made by carefully heating and stretching the tray material.

24 From practice, it has been found that patients may experience less tooth discomfort from tray pressures when using a tray with reservoirs built into the tray as described above. It is currently believed this is due to the fact that the teeth are not held as firmly by the tray, so "orthodontic" pressures experienced by teeth from tray indiscrepancies are minimized. The use of thin, soft tray materials further minimizes these "orthodontic" forces, compared to the harder plastics currently used in the art.

25 Reservoirs may also be creatively built into trays to provide additional bleaching agent to one or more teeth of an arch needing more whitening than others or to selected parts of a tooth needing more whitening than other parts.

26 To achieve most rapid results, it is recommended to use sustained release bleaching agents within the scope of the present invention in combination with the trays incorporating reservoirs. Nevertheless, it has been observed that bleaching occurs much more rapidly using conventional trays with sustained release bleaching compositions of the present invention than with existing bleaching agents. In addition, some increase in effectiveness has also been

observed when using existing bleaching agents with trays incorporating reservoirs compared to conventional trays without reservoirs.

27 Before commencing a home-use teeth bleaching treatment, it is recommended that the patient's teeth be clean of calculus and external stains. Restorations should be water tight and all dentin, particularly gingival dentin with potential or existing sensitivities, should be covered. It has been observed that exposed root surfaces may experience sensitivity from sustained release bleaching agent within the scope of the present invention. In many cases dentin may be covered with a layer of dentin bonding agent or sealant to prevent this.

28 Since most patients will want to complete their treatment as soon as possible, recommended treatment times start at approximately 18-20 hours a day. Patients are instructed to insert the tray loaded with fresh bleaching agent after each meal and before going to bed for most rapid results. Gum soreness or other patient discomfort has been reported more often for such accelerated treatment schedules that go longer than one to two days.

29 A second possible treatment schedule is to allow a break-time to occur between dinner and bed. This allows the patient to participate in evening social functions without wearing the tray. In addition, oral tissues are allowed to rest during the break-time.

30 Another recommended treatment schedule, particularly for those where the treatment may require more than one or two days, is to load and insert the tray only before bed and after lunch. This gives the teeth and soft tissues a rest for approximately two 4-5 hour intervals between the two longer treatment periods. Potential soreness is most often prevented this way and treatment time may only be extended 20% to 30% over the more accelerated treatment schedules.

31 Finally, for those patients who are often in public or those who have experienced moderate or greater problems of soreness, it is recommended that the tray be worn only at night. During sleep is the most productive single treatment time since less mouth activity "pumps" material from the tray.

32 Regardless of which treatment schedule is used, the use of sustained release dental bleaching compositions within the scope of the present invention provides a more constant level of bleaching agent adjacent the teeth than existing home-use bleaching systems. Even if patient compliance with existing home-use dental bleaching systems is such that fresh bleaching agent is added every hour, there still would be periodic high and low levels of bleaching agent adjacent the teeth. Since the amount and length of time the active bleaching agent is adjacent the teeth significantly influences the efficiency of the treatment, the sustained release bleaching compositions and methods of the present invention represent a significant improvement over existing home-use dental bleaching systems.

33 At the end of the bleaching treatment, a sustained release fluoride composition may optionally be administered to the patient. For convenience, the same tray may be used to treat the teeth with fluoride as was used to bleach the teeth. Such fluoride treatment regimens may include 3 or 4 two hour treatments over 1-2 days.

34 The following examples set forth various sustained release dental compositions within the scope of the present invention. These examples are intended to be purely exemplary and should not be viewed as limiting the scope of the present invention.

35 EXAMPLE 1

36 A sustained release dental bleaching composition within the scope of the present invention was prepared by combining the following ingredients:

Carbamide peroxide	13.2 gm	10%
Water	27.5 gm	21%
Glycerine	74.6 gm	57%
Carbopol 934P	9.5 gm	7%
Sodium hydroxide (50%)	6.5 gm	5%

37 The Carbopol 934P was obtained from B. F. Goodrich Company, Cleveland, Ohio. The carbopol was combined with the glycerine and then quickly mixed with the water. The glycerine enables the carbopol to be dispersed in the water. The carbamide peroxide was dissolved in the water before the glycerine-carbopol mixture was added to the water. The foregoing composition had a percentage of carbopol in water of about 25.7%. The sodium hydroxide was gradually blended into the homogeneous composition in order to raise the pH to an acceptable level.

38 The foregoing procedure produced a sustained release dental bleaching composition which was placed in a dental tray such as that described in connection with FIGS. 1-4 and worn by a patient for 9 hours. Subsequent examination of the patient's teeth indicated that the teeth had whitened 1-1.5 units on a Vita shade guide and that significant quantities of the sustained release bleaching composition was still observed in the application tray.

39 EXAMPLE 2

40 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	20
Water	20
Glycerine	40
Carbopol 934P	12
Sodium hydroxide	8

41 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 37.5%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

42 EXAMPLE 3

43 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent

Carbamide peroxide	5
Water	20
Glycerine	60
Carbopol 934P	10
Sodium hydroxide	5

44 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 33.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

45 EXAMPLE 4

46 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	10
Water	40
Glycerine	30
Carbopol 934P	12
Sodium hydroxide	8

47 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 23.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

48 EXAMPLE 5

49 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	18
Water	15
Glycerine	60
Carbopol 934P	4
Sodium hydroxide	3

50 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of

about 21.1%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

51 EXAMPLE 6

52 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	14
Water	10
Glycerine	70
Carbopol 934P	3.5
Sodium hydroxide	2.5

53 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 25.9%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

54 EXAMPLE 7

55 A sustained release dental bleaching composition within the scope of the present invention is made according to the procedure of Example 1, except that the ingredients are combined in the following amounts:

Ingredient	Weight Percent
Carbamide peroxide	5
Water	60
Glycerine	20
Carbopol 934P	10
Sodium hydroxide	5

56 The foregoing procedure results in a sustained release dental bleaching composition. The foregoing composition has a percentage of carbopol in water of about 14.3%. The composition possesses a high viscosity and excellent sustained release teeth bleaching activity.

57 EXAMPLE 8

58 A sustained release dental fluoride composition within the scope of the present invention was prepared by combining the following ingredients:

Ingredient	Weight	Weight Percent

Sodium fluoride	52 gm	1.1%
Water	1000 gm	21.5%
Glycerine	2980 gm	64.1%
Carbopol 934P	380 gm	8.2%
Sodium hydroxide (50%)	238 gm	5.1%

59 The foregoing ingredients are mixed according to the procedure of Example 1, except that sodium fluoride is used instead of carbamide peroxide. The fluoride concentration is preferably maintained at about 1.1% so that the free fluoride ion concentration is about 0.5%. The foregoing composition has a percentage of carbopol in water of about 27.5%. The foregoing procedure produces a sustained release dental fluoride composition suitable for use with a dental tray such as that described in connection with FIGS. 1-4.

60 Although the foregoing discussion has focused on sustained release dental bleaching or fluoride compositions, it will be appreciated that other sustained release dental compositions may also be prepared and used within the scope of the present invention. For instance, anticariogenic agents such as chlorhexidine gluconate and antimicrobial agents for treating periodontal pockets such as tetracycline may be incorporated into sustained release compositions. When the sustained release dental compositions are for treating soft tissues, the preferred tray design may need to be altered so that the tray overlaps the patient's gums.

61 In some cases, the sustained release dental agents may be used without a dental tray. For example, a sustained release dental composition having an antimicrobial agent may be expressed directly into periodontal pockets. In such compositions, it would be preferred to maximize the carboxypolymethylene concentration so that the effects of saliva dilution are minimized. In addition, mucosal adhesive materials may be added to the composition to further assist in retaining the composition within the periodontal pocket. Sustained release action may last from hours to days, depending on the patient's oral and salival activity.

62 From the foregoing, it will be appreciated that the present invention provides improved compositions and methods for treating tooth surfaces which facilitate patient compliance, so that the ultimate purpose of the treatment is realized.

63 Additionally, it will be appreciated that the present invention further provides sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced so that patient compliance is enhanced. The present invention also provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth.

64 It will be further appreciated that the present invention provides sustained release dental compositions and methods for bleaching a patient's teeth which provide noticeable lightening in a matter of days rather than weeks.

65 In addition, it will be appreciated that the present invention provides an improved dental tray having built in reservoirs for holding dental compositions for treating tooth surfaces which enhance the effectiveness of the dental treatment and patient comfort.

66 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning

and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A method for manufacturing a sticky dental bleaching composition adapted to be loaded into a dental tray when used to treat a patient's teeth, the method comprising the steps of:

(a) mixing together carboxypolymethylene, one or more polyols, and optionally water in sufficient quantities to form a matrix material into which a dental bleaching agent can be dispersed and so that the resulting dental bleaching composition will be sufficiently sticky and resistant to dilution by saliva such that the dental bleaching composition is capable of retaining the dental tray against the patient's teeth for at least about two hours without significant pressure being exerted by the dental tray;

(b) adding a base in order to adjust the pH of the matrix material to a desired pH;

(c) dispersing the dental bleaching agent within the matrix material.

2. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the one or more polyols include glycerine.

3. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the one or more polyols are selected from the group consisting of propylene glycol, sorbitol, polyethylene glycol, and mixtures thereof.

4. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the base comprises triethanolamine.

5. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the base comprises sodium hydroxide.

6. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the bleaching agent comprises carbamide peroxide.

7. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the bleaching agent comprises hydrogen peroxide.

8. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the pH is adjusted to within a range of about 5 to about 7.

9. A method for manufacturing a sticky dental bleaching composition as defined in claim 1, wherein the mixing step includes adding water to the matrix material.

10. A method for manufacturing a sticky dental bleaching composition as defined in claim 9, wherein the water is dispersed into the matrix material after first mixing together the carboxypolymethylene and one or more polyols.

11. A method for manufacturing a sticky dental bleaching composition adapted to be loaded into a dental tray when used to treat a patient's teeth, the method comprising the steps:

(a) mixing together carboxypolymethylene, one or more polyols, and optionally water in sufficient quantities to form a matrix material into which a dental bleaching agent can be dispersed and so that the resulting dental bleaching composition will be sufficiently sticky and resistant to dilution by saliva such that the dental bleaching composition will be able to retain the dental

tray against the patient's teeth for a period of at least about two hours without significant pressure being exerted by the dental tray;

(b) dispersing the dental bleaching agent within the matrix material; and

(c) adding a base in order to adjust the pH of the matrix material to a desired pH.

12. A method for manufacturing a sticky dental bleaching composition as defined in claim 11, wherein the one or more polyols include glycerine.

13. A method for manufacturing a sticky dental bleaching composition as defined in claim 11, wherein the base comprises triethanolamine.

14. A method for manufacturing a sticky dental bleaching composition as defined in claim 11, wherein the bleaching agent comprises carbamide peroxide.

15. A method for manufacturing a sticky dental bleaching composition as defined in claim 11, wherein the mixing step includes dispersing water into the matrix material after mixing together the carboxypolymethylene and glycerin.

16. A method for manufacturing a sticky dental bleaching composition as defined in claim 11, wherein the pH is adjusted to within a range of about 5 to about 7.

17. A method for manufacturing a sticky dental bleaching composition adapted to be loaded into a dental tray when used to treat a patient's teeth, the method comprising the steps:

(a) mixing together carboxypolymethylene and glycerin to form a matrix material into which a dental bleaching agent can be dispersed and so that the resulting dental bleaching composition will be sufficiently sticky and resistant to dilution by saliva such that the dental bleaching composition is capable of retaining the dental tray against the patient's teeth for at least about two hours without significant pressure being exerted by the dental tray;

(b) combining water into the matrix material in a manner that yields the sticky matrix material;

(c) adding a base in order to adjust the pH of the matrix material to within a pH of about 5 to about 7; and

(b) dispersing the dental bleaching agent within the matrix material.

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L12: Entry 2 of 2 File: USPT Dec 8, 1998

US-PAT-NO: 5846058
DOCUMENT-IDENTIFIER: US 5846058 A

TITLE: Dental trays having thin walls for increased patient comfort

DATE-ISSUED: December 8, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 433/216; 433/37, 433/80

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

28 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L12: Entry 1 of 2 File: USPT Dec 22, 1998

US-PAT-NO: 5851512
DOCUMENT-IDENTIFIER: US 5851512 A

TITLE: Dental compositions having a sticky matrix material for treating sensitive teeth

DATE-ISSUED: December 22, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 424/49; 433/215, 433/216, 433/226, 514/900, 514/944

ABSTRACT:

The present invention discloses sticky dental compositions and methods for treating sensitive teeth. For maximum comfort, an improved dental tray that is thin-walled, flexible and lightweight is used to hold the dental composition adjacent the desired tooth surfaces. The dental compositions include a sticky matrix material into which is dispersed a desensitizing agent such as KNO.sub.3 and other optional dental agents. The matrix material preferably includes carboxypolymethylene that has been partially neutralized with a base to reduce etching of the enamel. The carboxypolymethylene adds a unique stickiness to the dental composition which helps to adhere and retain the soft tray material against the patient's teeth.

23 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L13: Entry 2 of 2 File: USPT Jan 5, 1999

US-PAT-NO: 5855870
DOCUMENT-IDENTIFIER: US 5855870 A

TITLE: Method for treating sensitive teeth

DATE-ISSUED: January 5, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 424/49; 424/52, 424/53, 424/54, 433/215, 514/944

ABSTRACT:

The present invention discloses sticky dental compositions and methods for treating sensitive teeth. For maximum comfort, an improved dental tray that is thin-walled, flexible and lightweight is used to hold the dental composition adjacent the desired tooth surfaces. The dental compositions include a sticky matrix material into which is dispersed a desensitizing agent such as KNO.sub.3 and other optional dental agents. The matrix material preferably includes carboxypolymethylene that has been partially neutralized with a base to reduce etching of the enamel. The carboxypolymethylene adds a unique stickiness to the dental composition which helps to adhere and retain the soft tray material against the patient's teeth.

24 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L13: Entry 1 of 2 File: USPT Nov 16, 1999

US-PAT-NO: 5985249
DOCUMENT-IDENTIFIER: US 5985249 A

TITLE: Sticky dental compositions for adhering a passive-type dental tray over a person's teeth

DATE-ISSUED: November 16, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 424/49; 424/52, 424/53, 424/673, 433/215, 514/900, 514/944

ABSTRACT:

Sticky dental compositions which include a sticky, glue-like matrix material for treating a variety of tooth or gum ailments, and methods for treating teeth using such compositions. For maximum comfort, an improved dental tray that is thin-walled, flexible and lightweight is used to hold the sticky dental composition adjacent the desired tooth surfaces. The sticky dental compositions include a sticky matrix material into which is dispersed an appropriate dental agent, such as a bleaching agent, a desensitizing agent, and an anticariogenic agent, an antimicrobial agent. The matrix material preferably includes carboxypolymethylene that has been partially neutralized with a base to reduce etching of the enamel. The carboxypolymethylene adds a unique stickiness to the dental composition which helps to adhere and retain the soft tray material against the person's teeth.

22 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L14: Entry 1 of 2 File: USPT Jul 11, 2000

US-PAT-NO: 6086855
DOCUMENT-IDENTIFIER: US 6086855 A

TITLE: Methods for making scalloped dental trays for use in treating teeth with sticky dental compositions

DATE-ISSUED: July 11, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 424/49; 424/52, 424/53, 424/673, 433/215, 433/216, 514/900, 514/944

ABSTRACT:

The present invention discloses high viscosity sustained release dental compositions, such as tooth bleaching or fluoride compositions, for treating tooth surfaces. For maximum results, an improved dental tray having reservoirs for holding the dental composition adjacent the desired tooth surfaces is preferably used in combination with the sustained release dental composition. The sustained release dental compositions include a high carboxypolymethylene concentration which results in very high viscosity. The high level of carboxypolymethylene makes dilution of the dental compositions from saliva difficult and time consuming so that the compositions stay within the tray reservoirs, thereby providing sustained release. The concentrated carboxypolymethylene adds a unique tackiness to the dental composition which helps retain and seal the soft tray material against the patient's teeth.

20 Claims, 5 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L14: Entry 2 of 2 File: USPT Mar 14, 2000

US-PAT-NO: 6036943
DOCUMENT-IDENTIFIER: US 6036943 A

TITLE: Methods for treating a person's teeth using sticky dental compositions in combination with passive-type dental trays

DATE-ISSUED: March 14, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 424/49; 424/52, 424/53, 424/673, 433/215, 514/900, 514/944

ABSTRACT:

Sticky dental compositions which include a sticky, glue-like matrix material for treating a variety of tooth or gum ailments and methods for using such compositions. For maximum comfort, an improved dental tray that is thin-walled, flexible and lightweight is used to hold the sticky dental composition adjacent the desired tooth surfaces. The sticky dental compositions include a sticky matrix material into which is dispersed an appropriate dental agent, such as a bleaching agent, a desensitizing agent, and an anticariogenic agent, an antimicrobial agent. The matrix material preferably includes carboxypolymethylene that has been partially neutralized with a base to reduce etching of the enamel. The carboxypolymethylene adds a unique stickiness to the dental composition which helps to adhere and retain the soft tray material against the person's teeth.

20 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L19: Entry 2 of 2 File: USPT Jul 28, 1998

US-PAT-NO: 5785527
DOCUMENT-IDENTIFIER: US 5785527 A

TITLE: Stable light or heat activated dental bleaching compositions

DATE-ISSUED: July 28, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Jensen; Steven D.	Midvale	UT		
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 433/215; 424/53

ABSTRACT:

Dental bleaching compositions are made with a bleaching agent and a stable radiant-energy absorbing compound that acts as a bleaching agent activator. The dental bleaching compositions of the present invention can be one-part, pre-mixed compositions that do not require mixing at the time of treating a patient's teeth but which remain stable over time. The bleaching agent may consist of hydrogen peroxide, either in aqueous form or complexed with urea (carbamide peroxide) or sodium perborate. The bleaching agent activator includes hydrocarbons that are stable in the presence of the bleaching agent, which do not prematurely accelerate liberation of the bleaching agent, but which allow for selective activation of the bleaching agent by irradiation of the bleaching composition with radiant energy. The bleaching composition may optionally include a neutralizing agent to adjust the pH, a carrier to help provide proper consistency and potency, and a stabilizing agent to maintain maximum potency of the bleaching agent over time. The bleaching composition may also include a thickening agent to achieve a selected viscosity. The dental bleaching compositions may be adapted to be loaded into and delivered from a syringe.

40 Claims, 0 Drawing figures
Exemplary Claim Number: 1

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L19: Entry 1 of 2 File: USPT Oct 31, 2000

US-PAT-NO: 6139820
DOCUMENT-IDENTIFIER: US 6139820 A

TITLE: Delivery system for dental agents

DATE-ISSUED: October 31, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Fischer; Dan E.	Sandy	UT		
Jensen; Steven D.	South Jordan	UT		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Ultradent Products, Inc.	South Jordan	UT			02

APPL-NO: 09/ 360998 [PALM]
DATE FILED: July 26, 1999

PARENT-CASE:
RELATED APPLICATIONS This application is a continuation-in-part of U.S. application Ser. No. 09/181,103, filed Oct. 28, 1998 now issued U.S. Pat. No. 6,010,683, which is a continuation-in-part of U.S. application Ser. No. 08/964,502, filed Nov. 5, 1997 (abandoned). For purposes of disclosure, the foregoing applications are incorporated herein by specific reference.

INT-CL: [07] A61 K 7/16, A61 K 7/18

US-CL-ISSUED: 424/52; 424/49
US-CL-CURRENT: 424/52; 424/49

FIELD-OF-SEARCH: 424/49-88

PRIOR-ART-DISCLOSED:

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FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
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WO 82/03975	November 1982	WO	

ART-UNIT: 164

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

Toothpaste and other dentifrices formulated to include a volume increasing agent (density reducing agent) in order to significantly increase the volume of the toothpaste at the time it is dispensed onto a toothbrush. The inventive dental compositions preferably include a substantial quantity of entrained or trapped air or other gas in order to reduce the density, and hence the weight, of toothpaste actually placed within a person's mouth. The result is a reduction in the amount of active ingredients introduced into a person's mouth that might be ingested. The entrained air or other gas can also increase the availability of the active ingredient since the foamed composition increases the dispersibility of the active ingredients within saliva. The net effect is that a person decreases the actual amount of toothpaste without decreasing the volume, or visual amount, of toothpaste dispensed on the toothbrush. The density-reduction effect can alternatively be provided by means of a lower density filler in addition to, or instead of, the entrained gas. Such fillers typically include trapped air or voids.

36 Claims, 3 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 1

BRIEF SUMMARY:

1 BACKGROUND OF THE INVENTION

2 1. The Field of the Invention

3 The present invention is in the field of oral dentifrices, particularly in

4 the field of toothpastes. More particularly, the present invention relates to expanded toothpastes that have an increased volume-to-mass ratio in order to reduce the overall mass of toothpaste that is dispensed during each use. Such dentifrices deliver a lower absolute quantity of active ingredients while maintaining their legally required concentrations.

5 2. The Relevant Technology

6 Toothpastes and other dentifrices are widely used in America and throughout the world to provide good oral hygiene, to prevent tooth decay, remove stains and to treat or minimize other problems associated with oral hygiene, such as gum disease and foul breath odor. Toothpastes typically include an inert carrier

gel or paste, abrasive agents for removing plaque and other impurities found on a person's teeth, decay preventing medicaments, such as fluorides flavorants, surfactants, detergents, and other additives to provide a desired consistency and cleansing or medicinal activity. While many ingredients may be added or eliminated according to fads or perceived specialized needs, such as baking soda or tartar removing agents, modern toothpastes almost uniformly include fluoride in one form or another.

7 Fluoride has been medically proven to aid in the prevention of tooth decay. Typically, tooth decay causing agents generally comprise acids formed by bacterial breakdown of sugars in a person's mouth. Enamel treated with fluoride is much more resistant to such acidic attack compared to enamel that has not been treated with fluoride.

8 Nevertheless, there are some problems associated with the careless use of fluoride. While topical administration of fluoride to teeth provides reduced tooth decay, fluorides can be harmful if ingested in large enough amounts. Ingesting too much fluoride can lead to fluorosis and even death in some cases. Even if sublethal doses of fluoride are ingested, a person with fluorosis will often develop brown, mottled enamel and/or bone dyscrasia and other abnormalities. Even lower levels of fluoride ingestion can cause significant tooth discoloration. In higher amounts, the fluoride can affect the structural formation of teeth and cause inappropriate development, particularly in children.

9 While fluorosis can affect persons of any age, it is particularly pronounced in children. This is because children are much smaller and have far less body mass compared to adults. In addition, their bodies are in the development stage so that health problems have a more permanent and long-term effect. Therefore, a quantity of fluoride that is safe when ingested by an adult might be harmful if ingested by a child.

10 Moreover, because children are generally resistant to certain hygienic practices, including brushing their teeth on a regular basis, toothpaste manufacturers have deliberately developed toothpaste that taste good to encourage brushing. While this might have the beneficial effect of encouraging more brushing by children, it has the negative side effect of enticing children to swallow the toothpaste while they brush. Depending on the taste, children may intentionally or unintentionally swallow substantial amounts of toothpaste. Moreover, children generally do not understand that it is not proper to swallow toothpaste and might swallow large amounts even though many toothpastes for children include a warning label against ingestion of the product. Much of the problem stems from the tendency of children to apply too much toothpaste onto the brush.

11 Because of the known dangers associated with ingesting high levels of fluoride, toothpaste manufacturers generally recommend that children use only a pea-size quantity of toothpaste on the brush. A "pea-size" amount is typically about 1/3 the amount of toothpaste needed to fully cover an adult-sized toothbrush, as seen on advertisements generally. While such warnings are certainly proper, they are often not understood and ignored by both adults and children alike. In general, children simply do not understand that fluoride, while beneficial in very low doses, can be a poison at higher levels.

12 In real-life situations, most humans including children will lay a solid strip of toothpaste across the entire length of the toothbrush bristles. This is not surprising since we are all familiar with the ubiquitous television and print advertisements showing an inviting and generous quantity of toothpaste that runs the length of the toothbrush bristles, and even curls artistically and invitingly up and around on the end to form a solid strip across the length of the toothbrush with a "curly-Q" on one end. It is obviously in the toothpaste manufacturer's best interest to encourage the use of larger quantities of toothpaste, even though wasteful, in order to cause faster toothpaste depletion and more subsequent sales.

13 Because of this reality, the unfortunate result is that children have been found to develop fluorosis, which causes brown, mottled enamel. In addition, even more moderate doses of fluoride can create discoloration affect structural formation of teeth, and cause diseased teeth and bones. It is possible that the dangers of fluoride ingestion by children might actually outweigh the benefits of fluoride in fighting tooth decay, at least in some cases.

14 In addition to fluoride, toothpastes can include other ingredients which, while beneficial when applied topically in the mouth, might have unwanted side effects if ingested. Other ingredients in toothpaste that should not be ingested include surfactants, agents used to fight gum disease, tartar removal agents, bleachants, and other cleansing or disinfecting agents that are intended for topical application only.

15 In light of the foregoing, what are needed are compositions and methods for manufacturing toothpastes and other dentifrices which reduced the level of fluoride and other active ingredients that might be ingested by adults or children while still providing their beneficial effects.

16 It would be an additional improvement in the art to provide compositions and methods for manufacturing toothpastes and other dentifrices that provided the desired concentration of active fluoride and other dental agents while reducing the amount delivered.

17 Moreover, it would be a marked improvement in the art to provide compositions and methods for manufacturing toothpastes and other dentifrices that yielded compositions having an increased rate of dispersion of the fluoride and/or other active ingredients into saliva or water within a person's mouth compared to conventional toothpastes.

18 In particular, it would be a tremendous improvement in the art to provide compositions and methods for manufacturing toothpastes and other dentifrices that had increased dispersibility in saliva such that the active dental agent, such as fluoride, is more rapidly available to effect its beneficial activity.

19 Such compositions and methods for manufacturing improved toothpastes and other dentifrices are disclosed and claimed herein.

20 SUMMARY AND OBJECTS OF THE INVENTION

21 The present invention relates to compositions and methods which reduce the quantity, but not the concentration, of active ingredients delivered in a dentifrice in order to limit the danger associated with their possible ingestion. Particularly, the present invention relates to expanded toothpastes and other dentifrices having an increased volume-to-mass ratio in order to provide what looks and feels like a desired quantity of toothpaste, while reducing the actual mass that is delivered. This can be accomplished by incorporating substantial amounts of air or other gases, either as a foam or in the form of porous lightweight fillers, which shall hereinafter be referred to as a "density reducing component" or "density reducing means". In both cases, the density reducing means or component involves a substantial quantity of void space, or gas, incorporated within the toothpaste.

22 Besides reducing the density of the toothpaste, trapped or entrained gas has the additional benefit of increasing the dispersibility of active ingredients within the dentifrice in order for there to be greater contact time between the active ingredients and the person's teeth. Foamed toothpastes or other dentifrices have greatly increased solubility in saliva, which provides for greater availability and increased uptake of the active ingredients by the teeth or surrounding tissues. They also reduce the actual amount of active ingredients placed within the person's mouth, thus reducing the risk of ingesting lethal or unhealthy quantities of active dental medicaments, such as fluoride, by children and incapacitated adults.

23 Whereas toothpaste manufacturers provide warning labels that state that children should use only a pea-sized quantity of toothpaste on the brush, this message is in small print and is also drowned out by the more seductive and persuasive advertising campaigns showing a generous quantity of toothpaste laid out as a solid, voluptuous strip across the brush. Because it is natural for people to want more of a "good thing", people naturally waste toothpaste in spite of warning labels. Even if a manufacturer teaches the benefits of using less toothpaste and chooses not to advertise the use of greater quantities, the images provided by other manufacturers may nevertheless stick in the public's mind and overwhelm a particular manufacturer's good intentions.

24 In light of the foregoing, the advantage of incorporating gas within the toothpaste is that it creates the illusion of having a large quantity of toothpaste. This illusion allows persons, particularly young children, to safely use a longer strip of toothpaste across the toothbrush bristles. The inventive toothpaste will, however, contain a significant volume of entrained or trapped gas such that the overall mass of toothpaste and active ingredients dispersed therein will typically be much lower than the visual appearance. This allows a child, for example, to cover the toothbrush with a longer strip of toothpaste, while delivering a much smaller quantity of actual toothpaste, since the strip is a mixture of toothpaste and an inert gas, lightweight filler or both.

25 Not only does a foamed toothpaste create the illusory effect of having more instead of less, the foam can have the additional advantage of causing the toothpaste or other dentifrice to mix and disperse more rapidly with saliva. This causes the toothpaste to more quickly spread across the teeth and into crevices to provide faster cleaning and treatment of the teeth. Thus, foaming the toothpaste causes it to have the ability to gain proximity to tooth surfaces and crevices far more quickly than conventional toothpastes. Because most people on average brush for 60 seconds or less, it is important that the fluoride or other active ingredients are rapidly deployed over the surface of the person's teeth. Otherwise, their intended benefit may not be realized to the extent desired.

26 Alternatively, the desired benefits can be provided by using a toothpaste dispenser or formulation that has the ability to foam the toothpaste in situ, or just prior to use, by the person dispensing the toothpaste. For example, a container of toothpaste can be provided in conjunction with a small compartment of compressed gas that could be mixed into and entrained within the toothpaste during the dispensing process in order to foam the toothpaste at the time of use. Alternatively, the toothpaste can include entrained gas and be stored under pressure in an initially unfoamed state. Upon dispensing, the compressed gas will expand and cause in situ foaming of the toothpaste, similar to how shaving foam behaves. The final result would essentially be the same as using pre-foamed toothpaste, but with lower initial volume.

27 It should be understood that virtually any toothpaste known in the art can be modified so that it includes substantial quantities of entrained air or other gas in order to create the aforementioned benefits of foamed toothpaste. Therefore, while the present application discusses certain preferred methods and/or additives that facilitate the formation of stable foamed toothpaste, it should be understood that any conventional toothpaste known in the art that incorporates substantial quantities of entrained gas or air such that a toothpaste of greatly reduced mass can be dispensed onto the user's toothbrush will be within the scope of the present invention. An example of a toothpaste composition known in the art is set forth in U.S. Pat. No. 3,988,433 to Benedict. There are presently a wide variety of unfoamed toothpastes in the market sold by companies such as Colgate-Palmolive and Proctor & Gamble. For purposes of disclosing conventional unfoamed toothpaste compositions, the foregoing patent and known commercial toothpaste compositions are incorporated herein by specific reference.

28 In order to manufacture a stable foamed toothpaste containing entrained air or other gas, the toothpaste composition will preferably include an appropriate foaming agent, one or more gelling or thickening agents, and an additional stabilizing agent for maintaining a stable foam. Depending on the desired level of aeration and the desired toothpaste consistency, the concentrations of thickening agent and stabilizer would generally need to be adjusted for a desired toothpaste formulation. For example, toothpastes that include greater quantities of air or other gas will generally need to include greater concentrations of thickening or gelling agents in order to maintain a desired stiffness or consistency, since the inclusion of greater quantities of entrained gas will tend to soften or liquify toothpaste compositions that would otherwise be more stiff or gel-like if lesser quantities of air were entrained. Moreover, toothpastes that include more entrained gas will generally require greater quantities of the foam stabilizing agent.

29 In many cases, toothpastes also include surfactants such as sodium laurel sulfate that cause them to foam when mixing with saliva. This helps to more quickly dissolve the toothpaste in the saliva and increase the uptake of medicaments such as fluoride. In the present invention, providing a toothpaste that is already foamed will create a more easily dissolvable toothpaste, thus reducing the need for added detergents. This has the benefit of reducing the potential for ingestion of detergents. While not usually toxic in most individuals, detergents can nevertheless cause some gastro-intestinal discomfort.

30 In order to provide the foregoing benefits of increased dispersibility and availability of dispersed medicaments within toothpastes and other dentifrices, air or other gas may be entrained within the toothpaste or other dentifrice in an amount in a range from about 10% to about 90% by volume of the toothpaste or other dentifrice, preferably greater than about 25% by volume, more preferably greater than about 30% by volume, and most preferably greater than about 50% by volume of the toothpaste or other dentifrice. At lower concentrations of gas (i.e., below about 25% by volume), it will generally be necessary to include a second density reducing agent, such as a lightweight filler.

31 Instead of, or in addition to, incorporating substantial quantities of a gas, the inventive dentifrices may include the aforementioned lightweight solid filler. The term "lightweight solid" will refer to solid fillers that are generally insoluble in, and substantially impermeable to, the liquid components of the dentifrice and which preferably have a density less than about 0.50 g/cm.sup.3, more preferably less than about 0.3 g/m.sup.3, and most preferably less than about 0.1 g/cm.sup.3. Because the lightweight solids can act to displace a substantial portion of the active dentifrice without substantially reducing its concentration, lightweight solids can behave similarly to entrained gas as described herein.

32 Preferred lightweight solids are those which include substantial quantities of trapped air or other gas. Those which are most preferred will be substantially impermeable to liquids such that areas occupied by trapped air or other gas will resist invasion by the surrounding liquids. Lightweight fillers that readily absorbed liquids or gels into its porous areas, may not provide the desired density reducing function over time. However it is perfectly acceptable for the lightweight filler to break apart during use, such as during brushing, since their desired bulkifying function has already been carried once it has been dispensed onto a toothbrush or other scrubbing medium.

33 Examples of lightweight, low density solid fillers include, but are not limited to, foamed polystyrene particles, foamed polypropylene spheres, foamed polymeric beads, expanded perlite, expanded vermiculite, hollow glass spheres, hollow aluminum oxide spheres, hollow ceramic spheres, hollow plastic spheres, lightweight expanded geologic materials, and the like. In the case of "open-cell" fillers such as expanded perlite, it will

34 generally be desirable to treat such fillers with a sealer or coating in order

to prevent substantial absorption of surrounding liquids or gels when used in toothpastes. Nonporous fillers such as hollow glass spheres are preferred due to their impermeability to liquids and gels. In addition, larger but more rounded fillers provide excellent cleaning of plaque while being less abrasive and prone to scratch tooth enamel. More spherical fillers also provide for more stable foams in the event that it is desired to incorporate both entrained gas and a lightweight filler.

35 In addition to adding bulk and greatly reducing the density of the dental composition, the lower density solid filler can be selected to optionally impart an abrasive action such that it can assist the other abrasives included within the dental composition. The only limitation is that the lightweight solid filler should substantially reduce the density of the toothpaste but also be safe when placed within the oral cavity of a human.

36 In light of the foregoing, it is an object of the present invention to provide compositions and methods for manufacturing toothpastes and other dentifrices which reduce the amount of fluoride and other active ingredients that might be ingested by adults or children while still providing their beneficial effects.

37 It is a further object of the present invention to provide compositions and methods for manufacturing toothpastes and other dentifrices that provide the desired concentration of active fluoride and other dental agents while reducing the amount delivered by the dentifrice.

38 In addition, it is an object of the present invention to provide compositions and methods to provide manufacturing toothpaste and other dentifrices that yield compositions having an increased rate of dispersion of fluoride and/or other active ingredients into saliva or water within a person's mouth compared to conventional toothpastes.

39 It is a further object of the present invention to provide compositions and methods for manufacturing and other dentifrices that have increased solubility and dispersibility in saliva such that the active dental agent, such as fluoride, is more rapidly available to effect its beneficial action.

40 These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

DRAWING DESCRIPTION:

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to a specific embodiment thereof which is illustrated in the appended drawings. Understanding that these drawings depict only a typical embodiment of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which

FIG. 1 is a perspective view of the end of a toothbrush having a solid strip of a conventional toothpaste and showing a breakaway section of the toothpaste.

FIG. 2 is a perspective view of the end of a toothbrush having a "pea-size" amount of toothpaste.

FIG. 3 is a perspective view of the end of a toothbrush having a solid strip of a foamed toothpaste of the present invention and showing a breakaway section of the toothpaste.

DETAILED DESCRIPTION:

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

2 I. Introduction

3 The present invention relates to compositions and methods for creating expanded, lightweight toothpastes and other dentifrices in order to reduce the density of the toothpaste, or mass per unit volume. The benefit of doing this is at least twofold. First, reduced density toothpastes allow a person to dispense what appears to be a generous, full-bodied quantity of toothpaste onto the toothbrush as desired while reducing the actual quantity or mass of toothpaste being dispensed. This, in turn, reduces the quantity of active ingredients that might accidentally be ingested. Second, toothpastes which incorporate substantial void spaces increase the dispersibility of the toothpaste or other dentifrices in saliva or other aqueous systems, which accelerates or increases the availability of the active dental agents, particularly the uptake of fluorides. In other words the inventive dental compositions may at the same time provide increased effectiveness while lowering the risk of accidental poisoning by the active ingredients.

4 Fluorides and other medicaments are very useful in preventing tooth decay and treating other dental or oral ailments. The active ingredients in toothpaste and other dentifrices are usually safe when applied topically to tooth surfaces and/or gums. Medicaments found in toothpastes generally have little or no utility if ingested and can be harmful or even fatal if ingested in great enough quantities. This is particularly true in the case of children, who are generally much more sensitive to toxic doses of fluoride or other medicaments, or medicaments in which the threshold level of toxicity is far less in children due to their greatly smaller size and body weight compared to adults. By way of comparison, an adult weighing six times more than a child would have to ingest roughly six times more of a toxin in order for the toxin to have the same level of harm or toxicity.

5 In addition, whereas an adult has already gone through the growth stage, a child is still in the early stages of bodily development, which can create a whole array of developmental problems not experienced by adults. For example, in the early developmental stages of a child's teeth, particularly when baby teeth are replaced by permanent teeth, excessive fluoride, even if ingested in non-lethal amounts, can cause severe staining and mottling of the teeth. Excessive fluoride can also cause bone dyscrasia and other abnormalities, as well as inappropriate development of the teeth in general. For this reason, there has been growing concern that children should reduce the amount of fluoride intake in order to avoid the foregoing problems.

6 The reduction of fluoride in children has been problematic for a number of reasons, some political rather than scientific. First, the Food and Drug Administration of the United States has mandated that, in order to make the claim that a toothpaste contains fluoride, a manufacturer must include the mandated concentration range of fluoride, as measured in parts per million (between 950 ppm and 1150 ppm). By law "fluoride toothpastes" must include fluoride within the mandated range, regardless of whether the toothpaste is intended for adults or children. Therefore, toothpaste formulations for children are required by the government to have the same concentration of fluoride as adult compositions, notwithstanding the increased danger to children of such fluoride concentrations.

7 Instead of including lessor quantities of fluoride, the only identifiable difference between children's toothpaste and toothpastes made for adults is that children's toothpastes taste better. Some adult toothpastes often include unpleasant tasting ingredients, such as baking soda, tartar removing agents, plaque removing agents, and other medicaments. In contrast, to promote brushing

children's toothpaste are often manufactured to taste as delicious as possible. Unfortunately, better tasting toothpastes may also encourage a young child to swallow the toothpaste while brushing, or worse yet, eat the toothpaste even while not brushing. As a result, children on average ingest far more toothpaste than adults, the harm of which is further multiplied by the child's greatly reduced body weight. The potential risk is severe tooth maldevelopment, discoloration, and mottling of enamel, and in some cases, even death.

8 Although toothpaste manufactures now recommend that children only use a "pea-size" quantity of toothpaste on the brush, such warnings are unheeded by children who either cannot read or do not fully comprehend or appreciate the risks associated with ingesting toothpaste. Moreover, children are bombarded by television and print advertisements showing a generous, full-bodied strip of toothpaste across the entire length of the toothbrush bristles. Common experience has shown that children tend to be far more vulnerable to media campaigns than adults, and the mental impressions formed by seeing a large, full-bodied amount of toothpaste are far more powerful and persuasive than recommendations to use a pea-size quantity.

9 In light of this, the inventors have developed compositions and methods for manufacturing toothpastes that greatly reduce the actual quantity of fluoride or other medicaments that enter a person's mouth by way of toothpastes or other dentifrices, while giving the person the illusion of receiving a large quantity by allowing the person to dispense a full-bodied, solid strip of toothpaste across the toothbrush. Hence, a person can have the satisfaction of feeling like he or she has used a large, even wasteful, amount of toothpaste, while in reality the actual mass of toothpaste has been substantially reduced such that the person ends up using the recommended quantity. In addition, reducing the density of the toothpaste allows for the delivery of less actual fluoride or other active ingredient while maintaining the mandated or desired concentration of that ingredient.

10 In order to illustrate the utility of the invention, reference is now made to the drawings. FIG. 1 shows a solid, full-bodied quantity of a conventional toothpaste spread across the length of a standard adult toothbrush, with a swirled wrap-around portion of toothpaste as a cute accent on one side. Manufacturers have conditioned the public to believe that the toothpaste depicted in FIG. 1 is the satisfying and desired amount. FIG. 1 also includes a break-away section of the toothpaste showing the interior of the toothpaste, which can be seen to be a solid mass of gel or paste with no density reducing component. In reality, the quantity of toothpaste depicted in FIG. 1 is far greater than what is necessary to actually clean the teeth and provide adequate fluoride treatment.

11 In fact, common experience shows that when relatively large quantities of toothpaste are used, much of it is wasted by either falling from the person's mouth into the sink or by not being adequately dispersed throughout the person's saliva. In any event, because cleansing and fluoride treatment of teeth is largely a surface reaction, any toothpaste not directly in contact with the surface of the teeth is largely wasted and should be considered excessive. Moreover, in the case of young children or mentally disabled adults, excess toothpaste may often be ingested, either accidentally or intentionally. Thus, using the amount of toothpaste depicted in FIG. 1 is not only wasteful but potentially harmful.

12 FIG. 2 depicts a "pea-size" amount of a conventional toothpaste on the toothbrush, which is adequate for most people, not just children. Not only is this the recommended quantity for young children, it is also a realistic amount of toothpaste that will adequately cleanse an adult's teeth and provide sufficient fluoride treatment. Notwithstanding this, one has rarely if ever encountered a television or print ad showing a pea-size quantity of toothpaste on a toothbrush. The result is that people have been conditioned to feel a sense of deprivation if only a pea-size amount were used.

13 By way of comparison, the quantity of toothpaste required to cover a typically-sized adult toothbrush illustrated by FIG. 1 weights about 2.4 g, while the "pea-sized" amount illustrated by FIG. 2 weighs approximately 0.8 g. Thus, the pea-size amount recommended by children's toothpaste manufacturers is about 1/3 the size of the amount depicted in FIG. 1. The amount of fluoride delivered into a person's mouth by the amount illustrated by FIG. 1 is about 0.0026 g, while the amount within the pea-sized quantity illustrated by FIG. 2 is only about 0.00088 g, which is 1/3 as much.

14 FIG. 3 shows a large, full-bodied strip of a low density toothpaste made according to the present invention on top of an adult tooth brush. The lower density results from trapped air, either by way of direct air entrainment or by means of air or other gases encapsulated within a low density filler. By way of comparison, assuming that the amount of toothpaste depicted in FIG. 2 is 1/3 the size of the toothpaste depicted in FIG. 3, and also assuming that the toothpaste in FIG. 3 has only 1/3 the density of the toothpaste depicted in FIG. 2, the actual quantity or mass of the two toothpaste amounts depicted in FIGS. 2 and 3 is the same. On the other hand, the actual quantity of toothpaste depicted in FIG. 1 is three times the amount shown in FIG. 3, although they look the same. (Of course, FIG. 3 is merely illustrative of one embodiment in which the normal density of the toothpaste has been reduced by about 2/3. It should not be construed as in any way being limiting of the present invention.)

15 This clearly and succinctly demonstrates the beauty of the invention: the very satisfying and generous amount of toothpaste depicted in FIG. 3 looks the same as the amount in FIG. 1 but is, in actuality, the same as the pea-size amount depicted in FIG. 2. The result is that children and adults can be, in effect, fooled into thinking they are getting a standard quantity of toothpaste while, in reality, they are being limited to the equivalent of a pea-sized amount. Moreover, because only the density has been reduced, the toothpaste of FIG. 3 can have the same concentration of fluoride as the toothpastes of FIGS. 1 and 2, thus satisfying the demands of the FDA for fluoride toothpastes. The result is that a person gets to use "more" of a fluoride toothpaste having the mandated concentration of fluoride, while actually receiving a more limited actual quantity of fluoride that might be ingested.

16 If the only effect of entraining air were to reduce the risk of fluorosis and other ailments that can result from ingestion of fluoride and other medicaments in toothpastes and other dentifrices, then the dental compositions of the present invention would have great utility. Nevertheless, the inventors have found that foaming the dental compositions often increases the dispersibility and, hence, the availability of the active ingredients in the dentifrice, sometimes dramatically. It is postulated that this is due to the enhanced ability of foamed toothpastes or other dentifrices to dissolve or disperse within saliva and water such that the active medicaments, such as fluoride, are more quickly dissolved into the person's saliva and then dispersed over the tooth surfaces being treated.

17 One possible reason for this is that foamed toothpastes having entrained air or air pockets have a greatly increased effective surface area, which greatly increases the interface area between the toothpaste and saliva or water. This, in turn, can increase the solvating action of the saliva and/or water. The result is greater availability and uptake of fluoride and other medicaments, even though the actual amount of such medicaments has been reduced as a result of providing a lower density dentifrice. The result is greater efficiency per unit mass of the active ingredient. Because most people on average brush for 60 seconds or less, it is important that the fluoride or other active ingredients be rapidly deployed over the surface of the person's teeth. Otherwise, their intended benefit may not be realized to the extent desired.

18 The same or similar effect can be provided by certain lightweight fillers, such as hollow glass spheres, which can break apart and release tiny gas bubbles into the toothpaste during vigorous brushing in some cases. In addition, such fillers can provide enhanced cleaning of soft dental tissues and provide more

plaque-cleaning power while, at the same time, being more gentle and less abrasive on the tooth enamel.

19 II. Constituents Within the Inventive Dental Compositions

20 In order to manufacture dentifrice compositions of reduced density and increased bulk, the inventors have identified a number of components which aid in the formation of the inventive dentifrices and the stabilization of the air entrainment if necessary. It should be understood that virtually any toothpaste in the market or known in the art can be modified so that it includes substantial quantities of entrained or trapped air or other gases in order to create the aforementioned benefits of foamed toothpaste. Therefore, while the present application discusses certain preferred

21 methods and/or additives that facilitate the formation of toothpastes of reduced density, it should be understood that any conventional toothpaste known in the art that incorporates substantial quantities of entrained or trapped gas or air such that a toothpaste of greatly reduced mass can be dispensed onto the user's toothbrush will be within the scope of the present invention. An example of unfoamed and unexpanded toothpaste compositions known in the art is set forth in U.S. Pat. No. 3.988,433 to Benedict, as well as those commonly sold in the market, which have heretofore been incorporated by reference for purposes of disclosure.

22 A. Base Composition

23 The portion of the dental composition exclusive of the density reducing means or density reducing component comprises the "base composition". In other words, the "base composition" is that portion of the overall dental composition besides the density reducing means. In the case where the density reducing means comprises a gas, the base composition will supply essentially all of the mass or weight of the final dental composition, since the gas provides an insignificant quantity of mass or weight. In the case where the density reducing means includes or consists of a low density solid filler, the filler will provide a much lower percentage of the mass or weight compared to the base composition. The base composition comprises one or more dental agents dispersed within a carrier. In the case of a dental composition used to clean teeth, the base composition will preferably include an abrasive to assist in cleaning the person's teeth.

24 1. Dental Agents

25 The primary dental agent found in virtually all toothpastes is fluoride, which is an anticarious compound used to prevent tooth decay. Although very beneficial if used in appropriate quantities, fluoride can become dangerous if ingested in significant quantities. Examples of fluoride compounds useful as a decay prevention agent include, but are not limited to, sodium fluoride, potassium fluoride, calcium fluoride, magnesium fluoride, sodium fluorosilicate, stannous fluoride, stannous monofluorophosphate, sodium monofluorophosphate, and copper fluoride. Each of the foregoing fluoride compounds comprises a "fluoride ion source". A more complete discussion of fluoride compounds useful in fighting cavities may be found in U.S. Pat. No. 3,535.421 to Briner et al. For purposes of disclosure, the foregoing patent is incorporated herein by specific reference.

26 In order to deliver an effective amount of fluoride to a person's teeth, the foamed dental compositions of the present invention will include a fluoride concentration such that the fluoride ions are included in a range from about 10 ppm to about 3500 ppm, more preferably in a range from about 850 ppm to about 1150 ppm of fluoride ions. The exact amount of fluoride will depend on the solubility and dispersibility of fluoride and also FDA guidelines for fluoride-containing toothpaste. The FDA presently requires "fluoride toothpastes" to include at least 900 ppm of available fluoride ions.

27 Other dental agents or medicaments that can be included instead of, or in addition to, fluoride include antimicrobial agents that can be added to fight gum and periodontal diseases and desensitizing agents. Examples of antimicrobial agents include, but are not limited to chlorhexidine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methylbenzoate, propylbenzoate, and peroxides. Examples of desensitizing agents include, but are not limited to, potassium nitrate, citric acid, citric acid salts, strontium chloride, and the like.

28 2. Carrier

29 In order to deliver the appropriate concentration of dental agent to the user, the dental agent should be dispersed within a flowable substance that will allow for the dental agent to be dispensed onto e.g., a toothbrush. Because any toothpaste or dentifrice known in the art can be modified to include substantial quantities of entrained air or gas, the appropriate carrier could be any substance known in the art that has been found useful as a carrier in manufacturing toothpaste and tooth gels known in the art.

30 The term "carrier", as used herein, is defined as one or more compatible components which dilute and deliver the dental agent in appropriate quantities in an appropriate manner. Hence, appropriate carriers may include solid, liquid, gel-like, and gaseous components. Such components should be "compatible", which means that they are capable of being used together in a foamed composition without destabilizing or otherwise adversely affecting the foamed nature of the dental composition so that it will behave in the desired manner.

31 Examples of components found in carriers within conventional toothpastes are set forth in U.S. Pat. No. 3,988,433 to Benedict, the disclosure of which is incorporated herein by reference. Although Benedict may not necessarily use the term "carrier" to define the components found therein, any component other than the dental agent or medicament found in the composition of Benedict may fairly be referred to as a "carrier" component.

32 Materials that are used as carriers may also be used for other purposes in a dentifrice composition, such as acting as a humectant, abrasive, thickener, foaming agent, surfactant, and the like. Thus, although one of the components used in a toothpaste may be identified as providing a particular function, as used herein such other components will normally be classified under the rubric of being a "carrier" so long as it in some way aids in the delivery of an appropriate concentration of fluoride or other dental agent.

33 Carriers typically include a water-soluble gel or other material that gives bulk and the desired flow properties to the dental composition. Typically, a thickener or gelling material is dispersed in water or other solvent such as glycerine or polyethylene glycol to yield a carrier safe for use inside a person's mouth.

34 In order to protect the teeth and other oral tissues of the user, it will be preferable for the carrier to have a ph in a range from about 5 to about 9, more preferably in a range from about 6 to about 8. Examples of buffers and bases that can be used to adjust the pH include citrate, citrate-bicarbonate, and phosphate buffers, sodium hydroxide and amines.

35 3. Thickening Agents

36 A common constituent within a carrier will be a thickening, material, which may be used to provide bulk and a suitable consistency. Thickeners may be especially important in foamed dentifrice compositions since they may assist in stabilizing the entrained gas. They also may help keep the foamed composition firm and from having a liquid consistency. Hence, in a preferred embodiment, the foamed dentifrice compositions of the present invention will include a thickener as part of the carrier.

37 Appropriate thickeners may include either inorganic organic thickeners, or both. Inorganic thickeners that may be included in the dentifrice and toothpaste compositions of the present invention include fumed silicas dispersed in water, such as Cab-o-sil available from Cabot Corporation, and thickening silicas, including those available from W. R. Girace designated as Sylox 15.

38 Appropriate organic thickeners include natural and synthetic gums and colloids. Examples of organic thickeners include carrageenan (derived from Irish moss), xanthan gum, guar gum, other polysaccharide gums, sodium carboxymethyl cellulose, starch, polyvinyl-pyrrolidone, hydroxyethylpropylcellulose, hydroxybutylmethylcellulose, hydroxypropyl-methylcellulose, hydroxyethylcellulose, other cellulosic ethers, and carboxypolymethylene. Such materials are typically dispersed in water and/or other solvents, such as glycerine or polyethylene glycol.

39 Thickening materials will preferably be incorporated in the compositions of the present invention in a concentration in a range from about 0.05% to about 25% by weight of the composition, and preferably in a range from about 0.1% to about 10% by weight.

40 4. Abrasives and Polishes

41 The carrier will typically include one or more abrasive materials to help clean and polish the teeth. Because solids are inexpensive and can add bulk, they will normally comprise a substantial fraction of the carrier. Almost any granular solid or powder can act as an abrasive or polish, although certain solids are preferred in order to clean, yet avoid scratching, the tooth enamel. Conventional abrasives typically include salts having anti-tartar activity and which include, but are not limited to, dicalcium orthophosphate, calcium carbonate, silica and silicates beta-phase calcium pyrophosphate, sodium metaphosphate, long chain polyphosphates such as sodium hexametaphosphate and cyclic phosphates such as sodium trimetaphosphate as well as alkylmetatripolyphosphates such as sodium tripolyphosphate and potassium tripolyphosphate.

42 Mixtures of abrasives can also be used. The total amount of abrasive in the dentifrice of the present invention will preferably be in a range from about 0.5% to about 95% by weight of the dentifrice, and more preferably in a range from about 20% to about 60% by weight of the dentifrice. The abrasive and polish components should be distinguished from the optional lightweight filler components since conventional abrasives and polishes usually have a density greater than about 1 g/cm.sup.3. Thus, the term "abrasive" shall be construed to constitute an abrasive component other than a lightweight filler even though the lightweight filler may itself import abrasive activity. The term "abrasive" also includes polishes, which are generally very fine abrasives.

43 Polishing agents may be included in dentifrice compositions that contain siliceous materials, such as silica, which have a mean particle size up to about 10 microns and a very high surface area, e.g. in the range of 150-750 square meters/gram. Polishing agents differ from abrasives mainly in the former having a smaller particle size. A preferred polishing agent is a precipitated amorphous hydrated silica, such as Sorbosil AC-35 marketed by Crosfield Chemicals. Other polishing agents may also be employed, including peroxide reactive polishing agents such as sodium bicarbonate, calcium carbonate, as well as sodium metaphosphate, potassium metaphosphate, tricalcium phosphate, calcium phosphate dihydrate, anhydrous dicalcium phosphate, calcium pyrophosphate, magnesium orthophosphate, trimagnesium phosphate, alumina trihydrate, aluminum silicate, zirconium silicate, calcined alumina, and bentonite.

44 When polishing agents are present in the dentifrice composition of the present invention, they are preferably included in a range from about 10% to about 30%

by weight of the dental composition, more preferably in a range from about 5% to about 25% by weight.

45 5. Foaming and Stabilizing Agents

46 Foaming and stabilizing agents are typically included in prefoamed dental compositions, and aid in both entraining the gas to form the foam, and also assist in stabilizing the foam in many cases. As used in the present invention, the term "foaming agent" is defined as any substance that aids, or otherwise helps, the dentifrice composition become foamed or be maintained in a foamed state. Foaming agents generally work in conjunction with mechanical foaming devices, such as high speed mixing devices.

47 In order for pre-foamed dentifrice compositions to have a commercially practical shelf-life, the foamed compositions need to be shelf stable as a foam for prolonged periods of time and subsequently be ready for application. Stabilized foaming agents within the scope of the present invention should be non-toxic and should not contribute to the formation of carries. There are many foaming and stabilizing agents known that are capable of safely and effectively stabilizing foamed dentifrice compositions including, but are not limited to, soaps, proteins, extract of licorice root, fatty acids, and sulfite liquids.

48 6. Surfactants

49 Surfactants may be included in order to aid in dispersing the dentifrice composition throughout the oral cavity and also as a cleansing agent. They also may act as a foaming agent as discussed above. Surfactants help disperse the toothpaste within water and saliva found in the mouth during brushing. Surfactants may also improve the cosmetic acceptability and foaming properties of the dentifrice in the oral cavity.

50 Among the organic surfactants useful in the practice of the present invention are salts of the higher alkyl sulfates, such as sodium lauryl sulfate (SLS) or suitable alkyl sulfates having 8 to 18 carbon atoms in the alkyl group; sodium lauryl sulfoacetate, salts of sulfonated monoglycerides of higher fatty acids, such as sodium coconut monoglyceride, sulfonate or other suitable sulfonated monoglycerides of fatty acids of 10 to 18 carbons; salts of amides of high fatty acids. e.g.. 12 to 16 carbon atoms, with lower aliphatic amino acids, such as sodium-N-methyl-N-palmitoyl taurides sodium N-lauroyl-, N-myristoyl- and N-palmitoyl sarcosinates; salts of esters of fatty acids with isothionic acid or with glycerol monosulfate, such as the sodium salt of monosulfated monoglyceride of hydrogenated coconut oil fatty acids; salts of olefin sulfonates, e.g., alkene sulfonates or hydroxyalkene sulfonates or mixtures thereof having 12 to 16 carbon atoms in the carbon chain of the molecule; and soaps of higher fatty acids, such as those of 12 to 18 carbon atoms, e.g., coconut fatty acids. The cation of the salt is typically sodium, potassium or mono-, di- or triethanolamine.

51 Mixtures of two or more surfactants can be used if desired to obtain desired properties. Additional useful surfactants may include the non-ionic, cationic, zwitterionic, amphoteric non-soap organic synthetic detergents. A full range of suitable surfactants is disclosed in U.S. Pat. No. 3,988.433 issued to Benedict, the disclosure of which has been incorporated herein by reference.

52 Surfactants are preferably included in the dentifrice of the present invention is at a concentration in a range from about 0.5% to about 3% by weight, and more preferably from about 1% to about 2% by weight.

53 7. Humectants

54 It may be desirable to include a humectant material in a dentifrice or toothpaste composition in order to maintain moisture in the composition and keep the composition from becoming excessively stiff or hardened. Suitable humectants include, but are not limited to glycerin, sorbitol, and other

polyhydric alcohols that are suitable for human consumption. The humectant may be included in an amount up to about 40% by weight of the dentifrice composition. Alternatively, the dentifrice composition may contain up to about 40% by weight of a paraffin oil as a non-humectant softening agent.

55 8. Miscellaneous Components

56 Various other miscellaneous materials and components may be incorporated into the dentifrice composition of the present invention. Non-limiting examples of these various components include solid lightweight fillers, polishing agents, peroxides, colorants, dyes, flavoring and sweeteners.

57 Bicarbonate compounds, when included in the dentifrice components of the present invention as a cleansing or refreshening agent, are present at a concentration in a range from about 5% to about 20% by weight, and preferably in a range from about 8% to about 15% by weight. The particle size of the bicarbonate compounds can range from about 10 to about 300 microns. A particle size of about 20-60 microns is preferred, although the smaller particle size bicarbonate compounds can be more readily dispersed in the dentifrice carrier.

58 Peroxide compounds may be used as an ingredient in the dentifrice and toothpaste compositions of the present invention as a cleansing or whitening agent. When peroxide compounds are present in the dentifrice composition, the peroxide compounds are preferably included in a range from about 0.25% to about 5% by weight of the dentifrice composition, more preferably in a range from about 0.5% to about 2.0% by weight. Peroxide compounds suitable for use with the dentifrice and toothpaste compositions of the present invention include metal peroxides such as calcium peroxide, magnesium peroxide, and zinc peroxide.

59 Colorants such as pigments and dyes may be used in the practice of the present invention. Pigments include non-toxic water insoluble inorganic pigments such as titanium dioxide and chromium oxide greens, ultramarine blues and pinks and ferric oxides as well as water insoluble dye lakes

60 prepared by extending calcium or aluminum salts of FD&C dyes on alumina such as FD&C Green #1 lake, FD&C Blue #2 lake. FD&C #30 lake and FD&C # Yellow 15 lake. The pigments have a particle size in a range of about 0.1-500 microns, preferably about 0.1-50 microns, and are preferably included in a concentration of about 0.5% to about 3% by weight.

61 Dyes used in the practice of the present invention are generally food color additives presently certified under the Food Drug and Cosmetic Act for use in food and ingested drugs, including dyes such as FD&C Yellow No. 5 (sodium salt of 4-p-sulfophenylazo-1-p-sulfophenyl-5-hydroxypyrazole-3 carboxylic acid), FD&C Yellow No. 6 (sodium salt of p-sulfophenylazo-B-naphthol-6-monosulfonate), FD&C Green No. 3 (disodium salt of 4-{4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(4-hydroxy-2-sulfoniumphenyl)methylene}-[1-(N-ethyl-N-p-sulfobenzyl)-.delta.-3,5-cyclohexanediamine], FD&C Blue No. 1 (disodium salt of dibenzyldiethyldiaminotriphenylcarbinol trisulfonic acid anhydride), FD&C Blue No. 2 (sodium salt of disulfonic acid of indigotin) and mixtures thereof in various proportions. The preferred concentration of dye for the most effective result, when dyes are used in the present invention, is in an amount in a range from about 0.05% to about 10% by weight of the dentifrice compositions, and preferably from about 0.5% to about 2% of the total weight of the dentifrice composition.

62 Any suitable flavoring or sweetening material may also be incorporated in the dentifrice composition of the present invention. Examples of suitable flavoring constituents are flavoring oils, e.g., oils of spearmint, peppermint, wintergreen, sassafras, clove, sage, eucalyptus, marjoram, cinnamon, lemon, orange, and methyl salicylate. Suitable sweetening agents include sucrose, lactose, maltose, sorbitol, sodium cyclamate, perillartine, and sodium saccharin. Suitable flavor and sweetening agents may together comprise from

about 0.01% to about 5% of the dentifrice compositions.

63 Various other materials may be incorporated into the dentifrice composition of this invention. Non-limiting examples thereof include preservatives, silicones and chlorophyll compounds, antibacterial agents such as chlorhexidine, halogenated diphenyl ethers such as Triclosan, desensitizing agents such as potassium nitrate and potassium citrate and mixtures thereof. These adjuvants are incorporated in the dentifrice composition in amounts which do not substantially adversely affect the properties and characteristics desired, and are selected and used in proper amounts, depending upon the particular type of dentifrice component involved.

64 B. Density-Reducing Means

65 The terms "density-reducing means" and "density-reducing component" shall include entrained gas and/or lightweight filler components. In general, the density reducing means shall comprise the constituent that is primarily added to the base composition in order to reduce the density and increase the bulk and volume of the final dental composition. It should be understood that reducing the density is the same as increasing the volume and bulk per unit weight. In this way, the volume of the dental composition can be significantly or greatly increased by the density reducing means in order to allow a larger volume of the dental composition to be introduced onto a toothbrush, while reducing the actual amount of fluoride and other active ingredients actually delivered into a person's mouth.

66 In a first embodiment, the density reducing means will comprise entrained air or other gas. Entraining gas yields a final composition in which the final concentration of the fluoride or other active ingredient remains essentially the same as before the gas was added to the base composition. Moreover, gases are versatile because they may be readily entrained within dental compositions during manufacture or in situ at the time of use. Gases also tend to be inert and nonreactive vis-a-vis the active ingredients.

67 In conjunction with or at least partially in lieu of, the entrained gas, the density reducing means may include a solid, lightweight filler. The solid lightweight filler can be used to greatly decrease the density of the inventive dental compositions and provide lightweight bulk therein. A solid lightweight filler is defined as a material having a relatively low density or specific gravity, preferably less than about 0.5 g/cm.sup.3, more preferably less than about 0.3 g/cm.sup.3, and most preferably less than about 0.1 g/cm.sup.3. Because lightweight fillers can act to displace a substantial portion of the active dentifrice without substantially reducing the weight percent of the active dental agent, lightweight solids can behave similarly to entrained gas, as described herein.

68 Solid, low density fillers may be organic or inorganic. Examples of lightweight inorganic fillers include hollow glass spheres, hollow aluminum oxide spheres, hollow ceramic spheres, expanded perlite, expanded vermiculite, acrogels, expanded silica gels, lightweight expanded geologic materials, and the like. The term "hollow glass spheres" broadly encompasses spheres made from any known glass or glass-like substances, including but not limited to, silicon dioxides, soda-lime-borosilicates, aluminum oxides, silica-alumina ceramic glasses, and alkali-alumina-silicate ceramic glasses. Examples of lightweight organic fillers include cork, polystyrene foam particles, polyethylene particles, polypropylene particles, hollow plastic spheres, and other low density and/or expanded polymeric materials.

69 In the case of "open-cell" fillers such as expanded perlite, it will generally be desirable to treat such fillers with a sealer or coating in order to prevent substantial absorption of surrounding liquids or gels when used in toothpastes or other dentifrices. Nonporous fillers such as hollow glass spheres are preferred due to their impermeability to liquids and gels. In addition, relatively large diameter rounded fillers (e.g., having a diameter in a range

from about 20-150 microns) provide excellent cleaning of plaque while being less prone to scratch tooth enamel. More spherical fillers also provide far more stable foams in the event that it is desired to incorporate both entrained gas and a lightweight filler together within the lightweight dental compositions of the present invention.

70 A presently preferred hollow glass bubble or sphere useful in forming the expanded dental compositions of the present invention is available from 3M and sold as K1 series Scotchlite Glass Bubbles. These glass bubbles are made from soda-lime-borosilicate glass, have a target crush strength (90% survival) of 250 psi, and have a true density of 0.125 g/cc. The bubble size ranges from about 20 to about 120 microns, with the 50th percentile of size distribution being 65 microns.

71 In terms of particle size, such hollow glass bubbles are substantially larger than conventional abrasives used in toothpastes. Because conventional abrasives are generally quite jagged and abrasive, they are milled to much smaller sizes (usually less than 20 microns) in order to reduce their tendency to abrade teeth. Surprisingly, the much larger sized glass bubbles (e.g., 20-150 microns in diameter), while providing little if any abrasive power for cleaning stains from enamel due to their spherical shape and larger size, have been found to be particularly effective in removing plaque from teeth and soft tissues such as gums. Thus, toothpastes that include significant quantities of hollow glass spheres, or any type of large, spheroidal or otherwise round-edged filler, will provide enhanced plaque-removal capability while being generally less abrasive to enamel compared to conventional abrasives and polishes found in toothpastes.

72 Other hollow glass bubbles having varying compositions, crush strengths, densities and particle size distributions would also provide the aforementioned plaque-cleaning properties. In fact, virtually any round-edged, non-jagged particle would be less abrasive, although those having a relatively-large diameter (i.e., from about 10 to 150 microns) will be particularly effective in cleaning plaque from teeth and soft tissues.

73 The density reducing means are preferably included in an amount in a range from about 25% to about 90% by volume, more preferably greater than about 30% by volume, and most preferably greater than about 50% by volume.

74 III. Preparation of the Inventive Dental Compositions

75 The dentifrice and toothpaste compositions which are either foamed or which include a lightweight filler can be prepared using conventional techniques known in the art. For example, the dentifrice or toothpaste compositions can be prepared by blending each of the solid ingredients into a liquid carrier component, i.e., polyalkylene glycol, which is normally viscous at room temperature. Conventional adjuvants can then be included.

76 Once the desired dentifrice or toothpaste composition is formed, the composition can be foamed to form a foamed dentifrice or toothpaste composition within the scope of the present invention. Foam is produced in dentifrice or toothpaste compositions by introducing air or a gas into the toothpaste or dentifrice composition. Examples of foaming dentifrice or toothpaste compositions include foaming by mechanical means or chemical means. Alternatively, gas can be incorporated into the dental composition, which is then stored in compressed form under pressure. Upon dispensing the composition, the compressed gas will develop foam within the toothpaste upon being exposed to atmospheric pressure.

77 In one embodiment, the dentifrice composition is foamed prior to packaging (referred to as pre-foamed). When the dentifrice composition is foamed and then packaged, the dentifrice composition preferably comprises a foam stabilizing agent so that the foamed dentifrice composition is shelf-stable for a commercially practical period of time. The dentifrice composition is preferably foamed using mechanical means, such as high speed mixing or other agitation.

The foamed composition is then placed into a suitable container, such as a conventional toothpaste tube or pump container for storage. The inventive compositions should be stable as a foam: i) after mixing; ii) after storage of the composition for extended periods of time; and iii) after delivering a portion of the foamed composition from the container. Hence, upon opening and using a portion of the foamed toothpaste, the remaining foamed toothpaste can be resealed and reused while remaining as a stable foamed composition.

78 In another embodiment of the present invention, chemical foaming agents are used to foam the dentifrice composition prior to packaging. Chemical foaming agents create foam or entrained gas when the foaming chemicals are mixed together. An example of chemical foaming is the formation of carbon dioxide from the chemical reaction of aluminum sulfate and sodium bicarbonate. As with mechanical foaming, a foam stabilizer is preferably included with the chemically foamed dentifrice compositions in order to stabilize the foamed composition during storage, use and reuse.

79 In still another embodiment, the dentifrice composition may constitute a pressurized foaming composition. As used in the present invention, the term "pressurized foaming composition" is defined as a suspension of compressed gas voids within a liquid. A common example of a pressurized foaming composition is conventional shaving cream, wherein a gas is compressed in a container and upon release, a foamed material is produced. In correction with the present invention, the dentifrice composition is formed using conventional methods as discussed above. The dentifrice composition is then placed in a container with a suitable compressed gas, under pressure, using conventional compression techniques known in the art. Subsequently, when the dentifrice composition is dispensed from the container, the pressure of the gas causes the dentifrice composition to be dispensed as a foamed dentifrice composition. An example of a suitable propellant and foaming agent is carbon dioxide gas.

80 Alternatively, the dentifrices can be placed into a container under pressure along with foaming agents that will cause the dentifrice to foam upon being dispensed from the container and being exposed to the atmosphere. Similarly, a container of toothpaste can be provided in conjunction with a separate compartment of compressed gas, which gas can mix with the toothpaste during the dispensing process in order to foam the toothpaste at the time of use.

81 In yet another embodiment, air can be entrained into the initially unfoamed dental composition by means of the pumping action required to express the dental composition from the container within which it is stored.

82 Finally, some or all of the entrained air can be replaced with an appropriate low density, lightweight filler such as hollow glass spheres, hollow ceramic spheres, hollow and other low density plastic spheres, expanded geologic materials such as perlite which have been sealed to prevent substantial absorption of liquids, and the like. These fillers arc typically blended with the other components using low shear mixing in order to avoid breaking such fillers. Air and other gases can be entrained along with the lightweight fillers according to any appropriate method set forth above.

83 IV. Characteristics of the Inventive Dental Compositions

84 In order for the inventive expanded dental compositions to behave and seem like conventional toothpaste, the carrier should have a viscosity such that when substantial quantities of air and/or lightweight aggregates are entrained or mixed therein, the toothpaste will have a viscosity, yield stress, and other rheological properties such that it will flow from the storage container (e.g. a squeeze tube or syringe) onto the toothbrush and substantially maintain itself as a bead or line of composition across the tooth bristles for at least a short period of time. If the composition is too runny or nonviscous, the foam might collapse such that material could fall between the bristles of the toothbrush and cause the user to use more of the composition than is intended. On the other hand, the material should not be so stiff and viscous that it

cannot be easily expressed from the container without undue difficulty. In light of the disclosure set forth herein, one of ordinary skill in the art will know how to adjust the various components within the carrier material in order to obtain a stiffness and viscosity that will satisfy the aforementioned criteria.

85 Once the dental composition has been foamed, either during mixing to form a pre-foamed dental composition or in situ using compressed gas, the dental composition will include entrained gas or trapped air in a range from about 20% and about 90% by volume of the foamed composition, preferably greater than about 25% by volume, more preferably greater than about 30% by volume, and most preferably greater than about 50% by volume of the foamed toothpaste or dentifrice composition. The foregoing ranges are applicable when entrained air is the sole density reducing means.

86 The foregoing concentrations of entrained or trapped gas are measured at the time the dental composition is dispensed from the storage container onto a toothbrush or other applicator means. However, they do not constitute a limitation as to when foaming or expansion of the dental composition actually occurs. Though it might be said that the dental composition has a certain concentration of entrained gas "upon dispensing the dental composition from a storage container", it will be appreciated that the dental composition may either be pre-foamed or foamed in situ using, e.g., compressed gas.

87 In the event that a lightweight filler material is used in conjunction with, or in place of, entrained gas or air in order to reduce the density of the dental composition, the amount of lightweight filler will be such so as to maintain an appropriate rheology as described above. Moreover, the weight of the lightweight filler should be factored into the overall weight of the composition when determining the weight percent of the active dental agent. It may thus be necessary to increase the amount of the active ingredients by some degree to maintain the desired concentration due to the weight-increasing effect of the lightweight filler.

88 In order to achieve the benefits of the present invention, the lightweight filler material will be included within the composition, if included at all, in an amount such that the dental composition has a reduction in density, either alone or in combination with entrained air or other gas, in a range from about 20% to about 90% compared to the density of the "base composition" exclusive of the lightweight filler material. Preferably, the reduction in density will be greater than about 25% in

89 comparison to the base composition exclusive of the lightweight filler. More preferably, the reduction in density will be greater than about 30% and, most preferably, greater than about 50% in comparison to the base composition exclusive of the lightweight filler. Either entrained air and/or lightweight filler will comprise means for reducing the density of the dental composition.

90 As can be seen, the reduction in density caused by the lightweight filler, alone or in combination with entrained air, corresponds to the preferred ranges of the volume of entrained gas within foamed dental compositions that do not include lightweight fillers. As such, when both entrained gas and lightweight filler material are incorporated, it can readily be seen that the combined reduction in the density of the dental composition will be approximately the same as where it is reduced simply by incorporating gas or air, which contributes no mass while contributing high volume. This is also true for where a lightweight aggregate is used exclusively to reduce the density of the composition.

91 Because there is a direct correlation between the reduction of density and the increase of the bulk and volume of the dental composition per unit weight, it may be helpful to understand how the reduction in density increases the volume of the dental compositions according to the invention. A 20% decrease in the density of the base composition roughly increase the volume per unit weight by

about 25%, meaning that the final dental composition would have a volume that is 125% of the initial volume of the base composition. On the other hand, reducing the density by 90% would increase in the volume per unit weight of 900%, which means that the final dental composition would have a volume that is 1000% of the base composition. Likewise, a 25% decrease in the density constitutes a 33% increase of the initial volume such that the final volume is 33% of the initial volume of the base composition; a 33% decrease in the density yields a volume increase of about 50%; a 40% decrease in the density corresponds to a volume increase of about 67%; a 50% decrease in the density translates into a doubling of the volume, or an increase of 100%; and a decrease in density by 66.7% translates into a tripling of the volume, or an increase of 300%, which means that the final dental composition has 400% of the volume of the base composition, or 4 times the volume.

92 V. Examples of the Preferred Embodiments

93 The following examples are presented in order to mole specifically teach the preferred compositions and methods for forming and using low density dentifrices according to the present invention. The examples which have actually been made are written in past tense, while those that are merely hypothetical are written in present tense. Although some examples are hypothetical in nature, they are based on or derived from actual mix designs and conditions for making lower density dental compositions according to the present invention.

94 EXAMPLE 1

95 A base dental composition of normal density that was suitable for use in brushing or cleaning teeth was made by combining the following components:

Distilled water	21.6%
Glycerin	25%
Sorbitol	25.26%
Sodium Fluoride	0.25%
Sodium Benzoate	0.22%
Fumed Silica	3%
Abrasive Silica	19.5%
Aspartame	0.22%
Surfactants	2.6%
Xanthan gum	0.46%
Carbomer	0.3%
Flavors	1.0%
FD&C Colorants	0.59%

96 The base dental composition had a density of 1.4 g/cm.sup.3. Thereafter, the base dental composition was "spiked" with various quantities of hollow glass spheres in order to study the effect of adding a lightweight filler on the density of the resulting dental composition. The hollow glass spheres that were added were K1 series Scotchlite Glass Bubbles manufactured by 3M. These hollow glass spheres were made from soda-lime-borosilicate glass, had a target crush strength (90% survival) of 250 psi, and had a density of 0.125 g/cm.sup.3. The size distribution of the hollow glass spheres ranged from about 20 to about 120 microns, with the 50th percentile of size distribution being 65 microns.

97 To 100 parts of the base composition were added the following quantities of K1 series Scotchlite Glass Bubbles, measured in terms of parts and percent by volume, to form various "filled compositions". The resulting densities of the filled compositions are also listed:

Quantity Added	Volume Percent	Resulting Density
0 parts	0%	1.4 g/cm.sup.3
30 parts	15%	0.96 g/cm.sup.3
50 parts	25%	0.93 g/cm.sup.3
70 parts	35%	0.86 g/cm.sup.3
100 parts	50%	0.81 g/cm.sup.3

98 The above values were plotted and found to be essentially linear, meaning that there is an essentially linear relationship between the volume of added hollow glass spheres and the reduction in density within this concentration range. This is because of the tremendous disparity between the density of the base composition and that of the hollow glass spheres. Of course, since the hollow glass spheres do, in fact, add some additional weight to the dental composition, the relationship is not precisely linear, particularly at very high concentrations of hollow glass spheres (i.e. approaching 100% by volume).

99 The resulting filled dental compositions had a substantial reduction in density, which means that hollow glass spheres worked well in creating expanded, low density dental compositions that had greatly reduced mass per unit volume but which did not have substantially reduced concentrations of fluoride or other active ingredients.

100 The dental compositions having hollow glass spheres were tested to determine how well they cleaned teeth. Whereas the reduced density toothpastes were found to provide the same level of benefit with regard to the effects of fluoride treatment of teeth compared to conventional toothpastes, a surprising and unexpected benefit was increased plaque removal without any detectable increase in the abrasion of tooth enamel. It is believed that the increased size of the hollow glass spheres resulted in an enhanced ability of the dental composition to mechanically break up and disperse the plaque, thereby facilitating the dissolution and removal of plaque from the teeth and surrounding soft tissues by the solvents and surfactants present within the dental compositions. The rounded, non-jagged profile of the hollow glass spheres allowed for the aforementioned plaque removal without significant scratching of the enamel or irritation of the surrounding gums or gingival tissue.

101 EXAMPLE 2

102 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled water	30%
Glycerin	25%
Flavor and color	1.5%
Mannitol	15%
Sodium laurel sulfate	2%
Xanthan gum	1%
Abrasive silicon dioxide	25%
Fluoride source and preservative	0.5%

103 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. By way of example, if 20% by volume of a gas is entrained within the base composition, the resulting composition will have a density that is essentially 80% of the density of the base composition, or a density reduction of essentially 20% compared to the base composition. Increasing the volume of gas that is entrained reduces the density of the resulting composition by a corresponding amount. Entraining 90% by volume air will reduce the density by 90%, resulting in a final composition having 10% of the density of the base composition. In addition, because the mass of the entrained gas is negligible, the concentration of fluoride remains essentially the same in all cases.

104 In the case where some or all of the density reduction means comprises a low density filler, such as hollow glass or ceramic spheres, there will not be a 1:1 reduction in density as more low density of filler is added. However, the reduction of density is still substantial, even dramatic, so long as the density of the filler is substantially less than the density of the base composition. However, slight adjustments in the fluoride content may be necessary to maintain the desired fluoride concentration in the final dental compositions.

105 As discussed above, assuming that a "pea-size" amount is 1/3 the "normal amount", then it would be necessary to include enough density reduction means to reduce the density of the base composition by 2/3 to yield a final composition having only 1/3 the density of the base composition. In this way, one can use three times of the reduced density composition compared to the base composition and still put the same amount of fluoride into his or her mouth. Thus, an amount of reduced density toothpaste sufficient to cover an entire adult toothbrush (as depicted in FIG. 3) will, in reality, be equivalent to using a pea-size amount of the base composition (as depicted in FIG. 2).

106 However, because a child-sized toothbrush is roughly 50% the size of an adult toothbrush, the final dental composition only needs to have a density reduction of 1/3 , or 33%. In other words, because the volume of toothpaste required to totally cover the bristles of a child-sized toothbrush is about 50% of the volume required to cover an adult toothbrush, a "pea-size" amount is roughly 2/3 of the volume needed to cover a child-size toothbrush. Thus, assuming that a child will want to cover most or all of the bristles of a child-size toothbrush with toothpaste, a reduced-density dental composition would only need to have a density reduction of about 1/3 in order for the toothbrush-covering amount to be equivalent to the recommended pea-size amount using the foregoing assumptions.

107 EXAMPLE 3

108 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	20%
Propylene glycol	35%
Flavor and color	1.5%
Sorbitol	15%
Potassium laurate	1%
Polysorbate 60	1%
Carbomer 974 NF	1%

Abrasive aluminum oxide	25%
Fluoride source and preservative	0.5%

109 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

110 EXAMPLE 4

111 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	20%
Propylene glycol	20%
Polyethylene glycol 300	15%
Flavor and color	1.5%
Xylitol	15%
Octaoxyethlylene glycol monododecyl ether	1%
Polysorbate 20	1%
Pemulen TR-1 NF	2%
Abrasive aluminum oxide	25%
Fluoride source and preservative	0.5%

112 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

113 EXAMPLE 5

114 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Glycerin	31%
Polyethylene glycol 300	35%
Flavor and color	1.5%
Sodium saccharin	1%
Potassium laurate	1%
Polyalkylene oxide modified polydimethyl siloxanes	1%

Sodium oleate	2%
Fumed Silicon dioxide	2%
Abrasive calcium fluorosilicate	25%
Fluoride source and preservative	0.5%

115 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may

116 comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

117 EXAMPLE 6

118 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	63%
Flavor and color	1.5%
Phenylalanine	1%
Sodium decane sulfonate	1%
Carbomer 934	6%
Abrasive aluminum oxide	27%
Fluoride source and preservative	0.5%

119 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

120 EXAMPLE 7

121 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	22%
Propylene glycol	36%
Flavor and color	1.5%
Mannose	15%
Tetradecyltrimethyl ammonium bromide	1%
Sodium di-2-ethylhexyl sulfosuccinate	

	1%
Locust bean gum	1%
Abrasive titanium dioxide	22%
Fluoride source and preservative	0.5%

122 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

123 EXAMPLE 8

124 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Propylene glycol	57%
Flavor and color	1.5%
Fructose	15%
Carbomer 910	4%
Abrasive mica	22%
Fluoride source and preservative	0.5%

125 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

126 EXAMPLE 9

127 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	20%
Polyethylene glycol	35%
Flavor and color	1.5%
Sorbitol	15%
Abrasive silicon dioxide	20%
Mica	8%
Fluoride source and preservative	0.5%

128 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

129 EXAMPLE 10

130 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	20%
Glycerin	50%
Flavor and color	1.5%
Sucralose	1%
Sodium deoxycholate	2%
Abrasive aluminum oxide	25%
Fluoride source and preservative	0.5%

131 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is incorporated herein by reference.

132 EXAMPLE 11

133 Dental compositions suitable for use in brushing or cleaning teeth are made from a base composition having the following components, exclusive of density reduction means, expressed as a percentage by weight of the base composition exclusive of the density reduction means:

Distilled Water	23%
Polyethylene glycol	38%
Flavor and color	1.5%
Sorbitol	15%
Abrasive silicon dioxide	22%
Fluoride source and preservative	0.5%

134 The dental compositions made according to this example include density reduction means dispersed throughout the base composition in various amounts. The final dental compositions include various quantities of density reduction means in order for the density of the base composition to be reduced by 20-90% in 5% increments. The density reduction means may comprise both gases and low density solids as discussed herein. The remaining discussion of Example 2 is

incorporated herein by reference.

135 EXAMPLE 12

136 The density of any conventional toothpaste is reduced by adding one or more low density, lightweight fillers having a density less than 0.5 g/cc (preferably less than 0.3 g/cc, most preferably less than 0.1 g/cc) in order to reduce the density of the original toothpaste by 20-90% in increments of 5% selected from the following: hollow glass spheres (e.g., made from silica, soda-lime-borosilicate, aluminum oxide, silica-alumina ceramic, or alkali-alumino-silicate ceramic), hollow ceramic spheres, expanded perlite (treated with a sealer), expanded vermiculite (water resistant), aerogels (treated to be water resistant), expanded silica gels, cork, polystyrene foam particles, polyethylene particles. polypropylene particles, and hollow plastic spheres.

137 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS:

What is claimed and desired to be secured by United States Letters Patent is:

1. A dental composition for delivering a reduced quantity of fluoride ions into a person's mouth comprising:

a base composition including a fluoride ion source that provides from about 10 ppm to about 3500 ppm of fluoride ions, an abrasive solid, and a carrier selected from the group consisting of liquids, gels, pastes, and mixtures thereof, the base composition having a density; and

a density reducing component dispersed throughout the base composition and included in an amount so as to yield a final dental composition having a density that is at least about 30% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 30% relative to the base composition, wherein at least a portion of the density reducing component comprises a lower density solid filler,

wherein the dental composition has a rheology such that it can be expressed onto a toothbrush as a coherent mass and a sufficiently low level of abrasiveness such that it is suitable for use in daily tooth brushing.

2. A dental composition as defined in claim 1, wherein the density reducing component reduces is included in an amount so as to yield a final dental composition having a density that is at least about 50% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 50% relative to the base composition.

3. A dental composition as defined in claim 1, wherein the density reducing component reduces is included in an amount so as to yield a final dental composition having a density that is at least about 75% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 75% relative to the base composition.

4. A dental composition as defined in claim 1, wherein a portion of the density reducing component further comprises a gas that is dispersed throughout the base composition during mixing such that the dental composition is pre-foamed.

5. A dental composition as defined in claim 4, wherein the base composition further includes a foaming agent that stabilizes the pre-foamed dental composition such that the dental composition is capable of being stored for a desired period of time within a storage container without significant collapse of the foam.

6. A dental composition as defined in claim 1, wherein the density reducing component consists exclusively of the lower density solid filler.

7. A dental composition as defined in claim 1, wherein the lower density solid filler has a density less than about 0.5 g/cm.sup.3.

8. A dental composition as defined in claim 1, wherein the lower density solid filler has a density less than about 0.3 g/cm.sup.3.

9. A dental composition as defined in claim 1, wherein the lower density solid filler has a density less than about 0.1 g/cm.sup.3.

10. A dental composition as defined in claim 1, wherein the lower density solid filler imparts abrasive activity to the dental composition in addition to the abrasive solid within the base composition.

11. A dental composition as defined in claim 1, wherein the density reducing component comprises a mixture of a gas and the lower density solid filler.

12. A dental composition as defined in claim 1, wherein a portion of the density reducing component comprises initially compressed gas that causes the base composition to foam and expand to form the dental composition upon dispensing the base composition and compressed gas from a storage container onto a toothbrush.

13. A dental composition as defined in claim 12, wherein the compressed gas is premixed with the base composition and wherein the compressed gas and the base composition are initially stored together within a pressurized storage container.

14. A dental composition as defined in claim 12, wherein the compressed gas is stored in a compartment separate from, but in communication with, a storage container, containing the base composition such that the compressed gas is able to mix with the base composition and causes the base composition to foam and expand upon dispensing a mixture of the base composition and compressed gas.

15. A dental composition as defined in claim 1, wherein the fluoride ion source is included in an amount such that the dental composition provides fluoride ions in a concentration in a range from about 850 ppm to about 1150 ppm.

16. A dental composition as defined in claim 1 wherein the dental composition has a volume greater than about 133% relative to the volume of the base composition exclusive of the density reducing component.

17. A dental composition as defined in claim 1, wherein the dental composition has a volume greater than about 150% relative to the volume of the base composition exclusive of the density reducing component.

18. A dental composition as defined in claim 1, wherein the dental composition has a volume greater than about 300% relative to the volume of the base composition exclusive of the density reducing component.

19. A dental composition as defined in claim 1, wherein the dental composition has a rheology so that it may be expressed from a tube.

20. A reduced density dental composition comprising:

a base composition including a fluoride ion source that provides from about 10 ppm to about 3500 ppm of fluoride ions, all abrasive solid, and a carrier selected from the group consisting of liquids, gels, pastes, and mixtures thereof, the base composition having an density; and

a lower density solid filler, separate from the abrasive solid, having a density less than about 0.5 g/cm.sup.3 and being dispersed throughout the base composition in an amount so as to yield a final reduced density dental composition having a density that is at least about 30% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 30% relative to the base composition,

wherein the dental composition has a rheology such that it can be expressed onto a toothbrush as a coherent mass and a sufficiently low level of abrasiveness such that it is suitable for use in daily tooth brushing.

21. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler is included in an amount so as to yield a final reduced density dental composition having a density that is at least about 50% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 50% relative to the base composition.

22. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler is included in an amount so as to yield a final reduced density dental composition having a density that is at least about 75% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 75% relative to the base composition.

23. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler has a density less than about 0.3 g/cm.sup.3.

24. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler has a density less than about 0.1 g/cm.sup.3.

25. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler imparts abrasive activity to the dental composition in addition to the abrasive solid within the base composition.

26. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler comprises an inorganic filler material.

27. A reduced density dental composition as defined in claim 20, wherein the lower density solid filler comprises hollow glass spheres.

28. A reduced density dental composition as defined in claim 20, wherein the lightweight filler material comprises an organic filler material.

29. A reduced density dental composition as defined in claim 20, further including entrained gas.

30. A reduced density dental composition as defined in claim 20, wherein the fluoride ion source is included in an amount such that the dental composition provides fluoride ions in a concentration in a range from about 850 ppm to about 1150 ppm.

31. A reduced density dental composition comprising:

a base composition including a fluoride ion source that provides from about 10 ppm to about 3500 ppm of fluoride ions, an abrasive solid, and a carrier

selected from the group consisting of liquids, gels, pastes, and mixtures thereof, the base composition having a density; and

at least one of hollow aluminum oxide, ceramic, or glass bubbles separate from the abrasive solid and being dispersed throughout the base composition in an amount so as to yield a final reduced density dental composition having a density that is at least about 30% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 30% relative to the base composition,

wherein the dental composition has a rheology such that it can be expressed onto a toothbrush as a coherent mass and a sufficiently low level of abrasiveness such that it is suitable for use in daily tooth brushing.

32. A foamed dental composition for delivering a reduced quantity of flouride ions into a person's mouth comprising:

a base composition including a fluoride ion source that provides front about 10 ppm to about 3500 ppm of fluoride ions, an abrasive solid, and a carrier selected from the group consisting of liquids, gels, pastes, and mixtures thereof, the base composition having a density, and

a mixture of a gas and a lower density solid dispersed throughout the base composition, wherein the mixture of the gas and lower density solid is included in an amount so as to yield a final foamed dental composition having a density that is at least about 30% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 30% relative to the base composition,

wherein the dental composition has a rheology such that it can be expressed onto a toothbrush as a coherent mass and a sufficiently low level of abrasiveness such that it is suitable for use in daily tooth brushing.

33. A foamed dental composition as defined in claim 32, wherein the mixture of the gas and lower density solid is included in an amount so as to yield a final foamed dental composition having a density that is at least about 50% less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 50% relative to the base composition.

34. A method for delivering a reduced quantity of fluoride ions into a person's mouth, comprising:

(a) expressing a quantity of a reduced density dental composition as a coherent mass onto a tooth brush suitable for daily brushing, wherein the dental composition has a sufficiently low level of abrasiveness such that it is suitable for use in daily tooth brushing and includes:

(i) a base composition including a fluoride ion source that provides form about 10 ppm to about 3500 ppm of fluoride ions, an abrasive solid, and a carrier selected from the group consisting of liquids, gels, pastes, and mixtures thereof, the base composition having a density; and

(ii) a density reducing component dispersed throughout the base composition and included in an amount so as to yield a final dental composition having a density that is at least about 30 less than the density of the base composition in order to thereby reduce the quantity of fluoride ions delivered per unit volume of the dental composition by at least about 30% relative to the base composition, wherein at least a portion of the density reducing component comprises a lower density solid filler; and

(b) brushing the person's teeth using the tooth brush and the dental composition.

35. A method as defined in claim 34, wherein the density reducing component further includes a gas.

36. A method as defined in claim 34, wherein the density reducing component consists exclusively of the low density solid filler.

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L20: Entry 2 of 2 File: USPT Apr 11, 2000

US-PAT-NO: 6048202
DOCUMENT-IDENTIFIER: US 6048202 A

TITLE: Polymerizable isolation barriers with enhanced tissue adherence and methods for forming and using such barriers

DATE-ISSUED: April 11, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Jensen; Steven D.	Midvale	UT		
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 433/136; 433/215

ABSTRACT:

The polymerizable dental isolation barrier has a monomer and an initiator. The barrier composition has at least one additive including a polymer strength reducer, a wet tissue adherence accentuator, and a reflective material The polymer strength reducer is an organic compound that prevents complete polymerization. The tissue adherence accentuator enables the barrier to adhere to a dental substrate ever after polymerization. The reflective material lowers the reaction rate and lowers the production of excess heat to reduce patient discomfort and to avoid tissue damage.

50 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L20: Entry 1 of 2 File: USPT Jul 11, 2000

US-PAT-NO: 6086370
DOCUMENT-IDENTIFIER: US 6086370 A

TITLE: Polymerizable isolation barriers containing reflective materials and methods for forming and using such barriers

DATE-ISSUED: July 11, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Jensen; Steven D.	Midvale	UT		
Fischer; Dan E.	Sandy	UT		

US-CL-CURRENT: 433/136; 433/215

ABSTRACT:

The polymerizable dental isolation barrier has a monomer and an initiator. The barrier composition has at least one additive including a polymer strength reducer, a wet tissue adherence accentuator, and a reflective material. The polymer strength reducer is an organic compound that prevents complete polymerization. The tissue adherence accentuator enables the barrier to adhere to a dental substrate even after polymerization. The reflective material lowers the reaction rate and lowers the production of excess heat to reduce patient discomfort and to avoid tissue damage.

56 Claims, 4 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 2

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L21: Entry 1 of 1 File: USPT Oct 25, 1988

US-PAT-NO: 4780083
DOCUMENT-IDENTIFIER: US 4780083 A

TITLE: Compound and dental applicator for enamel removal

DATE-ISSUED: October 25, 1988

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Croll; Theodore P.	Doylestown	PA	18901	

US-CL-CURRENT: 433/216; 424/49, 433/142

ABSTRACT:

This invention relates to dentistry, and more particularly to cosmetic dentistry, where for aesthetic objectives it is desirable to remove a small amount of the patient's tooth enamel to modify tooth color. A procedure is described using an applicator and compound which provides accelerated treatment time in stripping away a sufficient amount of the outer layer of the tooth enamel to provide the necessary tooth color modification. The applicator has two functional ends. One end has a containment pocket for holding the compound, and a second end for high pressure scouring of the tooth enamel. The compound comprises an enamel softening acid, such as hydrochloric acid, in the concentration range of between 6%-16% in combination with an abrasive particulate material. The abrasive material should have a hardness greater than 6.0 as measured on the Mohs hardness scale for greatest effectiveness.

8 Claims, 4 Drawing figures
Exemplary Claim Number: 5
Number of Drawing Sheets: 1

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L23: Entry 1 of 2 File: DWPI Oct 3, 1991

DERWENT-ACC-NO: 1991-310503
DERWENT-WEEK: 200114

TITLE: Sustained release compsn. for bleaching tooth surfaces - comprises bleach in high viscosity matrix contg. carboxy:polymethylene, also for delivering anticariogenic or antimicrobial agents

INVENTOR: FISCHER, D E

PATENT-ASSIGNEE:

ASSIGNEE	CODE
ULTRADENT PROD INC	ULTRN
ULTRADENT PRODUCTS	ULTRN
ULTRADENT PROD	ULTRN
FISCHER D E	FISCI

PRIORITY-DATA: 1990US-0553168 (July 13, 1990), 1990US-0497934 (March 22, 1990), 1991US-0719128 (June 20, 1991), 1992US-0951713 (September 24, 1992), 1991US-0797419 (November 22, 1991), 1991US-0718210 (June 20, 1991), 1993US-0099247 (July 28, 1993), 1993US-0985700 (December 2, 1993), 1995US-0378315 (January 25, 1995), 1996US-0722549 (September 27, 1996), 1992US-0985700 (December 2, 1992), 1996US-0722553 (September 27, 1996), 1996US-0721008 (September 26, 1996), 1996US-0721048 (September 26, 1996), 1996US-0722397 (September 30, 1996), 1996US-0718986 (September 26, 1996)

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DESIGNATED-STATES: AU CA JP BE CH DE DK ES FR GB GR IT LI LU NL SE AT BE CH DE DK ES FR GB GR IT LI LU NL SE AT BE CH DE DK ES FR GB GR IT LI LU NL SE

CITED-DOCUMENTS:US 3499844; US 3657413 ; US 4032627 ; US 4518721 ; US 4839157 ; EP 202359 ; EP 325267

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JP 3113182B2	March 18, 1991	1995JP-0249671	
JP 3113182B2		JP 8113520	Previous Publ.

09224963 A INT-CL (IPC): A61 C 3/00; A61 C 5/00; A61 C 9/00; A61 C 13/20; A61 C 15/00; A61 C 19/06; A61 K 6/00; A61 K 6/10; A61 K 7/16; A61 K 7/18; A61 K 7/20; A61 K 47/32; C01 B 15/00; C01 B 15/10; C07 C 275/00

RELATED-ACC-NO: 1999-080337;1999-105026 ;2000-061080 ;2000-269869 ;2000-513995 ;2001-137359

ABSTRACTED-PUB-NO: EP 522087B
BASIC-ABSTRACT:

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.
ABSTRACTED-PUB-NO:

US 5098303A
EQUIVALENT-ABSTRACTS:

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn.

Also new are (1) dental trays for delivering an agent to the surface of teeth

comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) w.r.t. total compsn., or 20-30 wt.% w.r.t. total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns. have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

EP-522087 A method of bleaching a patient's teeth as a cosmetic treatment, which comprises: (a) providing a dental tray configured to cover a patient's teeth surfaces to be bleached and configured to hold a quantity of dental bleaching composition; (b) placing a quantity of dental bleaching composition within the dental tray, the dental bleaching composition comprising: a quantity of dental bleaching agent capable of bleaching vital tooth surfaces in contact with the dental bleaching agent; and a matrix material into which the dental bleaching agent is dispersed, the matrix material conferring tacky characteristics on the composition, and including carboxypolymethylene in an amount such that the matrix material has a sufficiently high viscosity and low solubility in saliva that the matrix material provides for the bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 3 hours; (c) positioning the dental tray over the patient's teeth surfaces so that the dental bleaching composition is in contact with the patient's teeth surfaces to be bleached; (d) retaining the dental tray in position over the patient's teeth surfaces by virtue of the tacky characteristics of the bleaching composition; and (e) removing the dental tray from the patient's teeth.

Patients teeth are bleached using a dental tray which covers a patient's teeth surfaces and configured to hold dental bleaching compsn.

Process comprises (a) placing bleach compsn. within the tray; (b) placing it over patient's teeth surfaces so that part of the compsn. contacts teeth; (b) allowing it to remain over teeth surfaces; and (d) removing the tray from teeth. Bleaching compsn. comprises (1) dental bleaching agent to bleach vital tooth surfaces; and (ii) 3.5-12 wt%) carboxypolymethylene matrix into which (i) is dispersed.

ADVANTAGE - Sustained release is enabled of high viscosity bleaching compsn.

US 5234342A

Patient's teeth are bleached using a dental tray configured is cover teeth surfaces and hold sustained release dental bleaching compsn..

Bleaching comprises (a) placing bleaching compsn. with the tray,. (b) positioning over teeth surfaces so part of it contacts teeth surfaces; (c) allowing it to remain there, so that bleaching agent remains active whilst tray is in position; and (d) removing the tray.

Bleaching compsn. pref. comprises (e) sustained release dental bleaching agent to bleach vital tooth surfaces when in contact; and (b) a matrix of carboxy polymethylene in amt. 3.5-12 wt.% w.r.t. compsn. into which (a) is dispersed.

ADVANTAGE - Conc. carboxy polymethylene adds a unique tackiness to the compsn. and helps retain and seal the soft tray material against teeth.

US 5376006A

Teeth bleaching comprises obtaining a dental tray configured to cover at the tooth surfaces and hold dental bleaching compsn. and contacting with the teeth. The dental bleaching material is dispersed in a matrix of carboxy polymethylene (Carbopol 934P), etc. to give high viscosity and low sol. in saliva for contact time of 2+ hrs. and the matrix is tachy to retain and hold the dental tray on the tooth, without mechanical pressure, giving sustained release. Matrix material comprises 3.5-12 wt.% of bleaching agent, pH is 5-7. Bleaching agents include carbamide

peroxide and H2O2. Soft dental trays with reservoirs for the compsn. are vacuum-cast from alginate moulds in shapes to avoid the gingivial surfaces.

ADVANTAGE - Convenient for home use tooth bleaching and fluoride treatment.

US 5409631A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5725843A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5746598A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5759037A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2)

compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5759038A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5770105A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5770182A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

US 5846058A

Dental bleaching compsn. (A) comprises (1) amt. of agent (I) able to bleach vital tooth surfaces dispersed in (2) a matrix material (II) which has carboxy polymethylene (III) at 3.5-12 wt.% of the compsn. Also new are (1) dental trays for delivering an agent to the surface of teeth comprising a synthetic mould of the teeth with reservoir(s) for holding the agent in contact with the teeth; and (2) compsns. similar to (A) but having an anticariogenic agent (IV) or antimicrobial agent (V) in place of (I). Pref. (II) contains 4.5-10 (6-8)% (III) wrt total compsn., or 20-30 wt.% wrt total amt. of water. The compsns. are adjusted with base to pH 5-7. (I) is carbamide peroxide at 3-20 (4-15)% or H2O2 at 2-10 wt.%.

USE/ADVANTAGE - (A), and related compsns., have high viscosity (so are not easily diluted by saliva) and provide sustained release of active agent. (III) renders the compsn. tacky, so helps to retain and seal the tray against the teeth. (A) provides more effective bleaching than known compsns. of similar (I) content; do not need continuous replacement; provide a more consistent level of (I) on the tooth, and whiten the teeth in a few days rather than weeks.

WO 9114650A

CHOSEN-DRAWING: Dwg.0/5 Dwg.1/4 Dwg.1/4 Dwg.1/4 Dwg.0/5

TITLE-TERMS: SUSTAINED RELEASE COMPOSITION BLEACH TOOTH SURFACE COMPRISE BLEACH HIGH VISCOSITY MATRIX CONTAIN CARBOXY POLYMETHYLENE DELIVER ANTICARIES ANTIMICROBIAL AGENT

DERWENT-CLASS: A96 B05 D21 E19 P32

CPI-CODES: A04-F01A; A12-V04B; B02-T; B04-C03B; B05-A01B; B07-D13; B10-A04; B12-A01; B12-L03; D08-A; E10-A04B; E31-E;

CHEMICAL-CODES:

Chemical Indexing M1 *05*
Fragmentation Code
H7 H714 H721 J0 J011 J1 J171 M210 M212 M262
M281 M320 M417 M423 M424 M431 M510 M520 M530 M540
M740 M782 M903 N103 P913 R052 V742

Chemical Indexing M2 *01*
Fragmentation Code
K0 L4 L432 M280 M320 M416 M424 M431 M620 M740
M770 M782 M903 M904 M910 N103 P912 P913 Q613 R052
Specfic Compounds
04169M

Chemical Indexing M2 *00*
Fragmentation Code
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M391 M416 M424 M431 M620 M740 M782 M903 M904 M910
N103 P913 R052
Specfic Compounds
00113M

Chemical Indexing M2 *00*
Fragmentation Code
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P912 P913 R052
Specfic Compounds
01717M

Chemical Indexing M2 *00*
Fragmentation Code
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N103 P220 P912 P913 R052 V0   V201
Specfic Compounds
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Chemical Indexing M3 *01*
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    Specfic Compounds
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Chemical Indexing M3 *00*
    Fragmentation Code
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    M391 M416 M424 M431 M620 M740 M782 M903 M904 M910
    N103 P913 R052
    Specfic Compounds
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Chemical Indexing M3 *00*
    Fragmentation Code
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    C807 M411 M424 M431 M740 M782 M903 M904 M910 N103
    P912 P913 R052
    Specfic Compounds
    01717M

Chemical Indexing M3 *00*
    Fragmentation Code
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    H4   H403 H441 H462 H8   J0   J011 J3   J351 J5
    J563 M210 M211 M240 M273 M281 M282 M320 M414 M424
    M431 M510 M520 M531 M540 M740 M782 M903 M904 M910
    N103 P220 P912 P913 R052
    Specfic Compounds
    00210M

Chemical Indexing M6 *09*
    Fragmentation Code
    M903 P220 P912 P913 Q503 Q613 R052 R111 R200 R305
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UNLINKED-DERWENT-REGISTRY-NUMBERS: 0095U; 0113U ; 0123U ; 0210U ; 1514U ; 1717U ; 1732U ; 1740U

POLYMER-MULTIPUNCH-CODES-AND-KEY-SERIALS:
Key Serials: 0224 0231 0411 1235 2318 2378 2458 2463 2507 2509 2545 2556 2575 2622 2654 3252 2675 2682 2761 3289 2790

Multipunch Codes: 014 034 04- 074 075 076 135 137 27& 289 316 332 381 398 427 44& 455 456 459 460 476 512 525 532 537 54& 551 560 561 57- 575 58& 596 597 600 609 62- 645 724 726 728

SECONDARY-ACC-NO:
CPI Secondary Accession Numbers: C1991-134474

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L1: Entry 30 of 852 File: USPT May 28, 2002

US-PAT-NO: 6394314
DOCUMENT-IDENTIFIER: US 6394314 B1

TITLE: Double-barreled syringe with detachable locking mixing tip

DATE-ISSUED: May 28, 2002

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Sawhney; Ravi K.	Calabasas	CA		
Hussey; Lance	Sherman Oaks	CA		
Hayman; Robert G.	Pacific Palisades	CA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Discus Dental Impressions, Inc.	Culver City	CA			02

APPL-NO: 09/ 581344 [PALM]
DATE FILED: June 9, 2000

PARENT-CASE:
CROSS-REFERENCE TO RELATED APPLICATION The present application relates to PCT application Ser. No. PCT/US99/23604, filed Oct. 12, 1999; which claims the benefit of Ser. No. 09/170,146, filed Oct. 12, 1998, and both having the title "DOUBLE-BARRELED SYRINGE WITH DETACHABLE LOCKING MIXING TIP".

PCT-DATA:

APPL-NO	DATE-FILED	PUB-NO	PUB-DATE	371-DATE	102(E)-DATE
PCT/US99/23604	October 12, 1999	WO00/21842	Apr 20, 2000	Jun 9, 2000	Jun 9, 2000

INT-CL: [07] B67 D 5/52

US-CL-ISSUED: 222/137; 222/145.6, 222/153.09, 222/386, 222/459, 239/399
US-CL-CURRENT: 222/137; 222/145.6, 222/153.09, 222/386, 222/459, 239/399

FIELD-OF-SEARCH: 222/137, 222/145.6, 222/153.09, 222/386, 222/459, 239/399

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

Search Selected Search ALL

PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
3166221	January 1965	Nielsen	222/137
3330444	July 1967	Raypholtz	222/137
4538920	September 1985	Drake	366/177
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4767026	August 1988	Keller et al.	222/137
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RE36235	June 1999	Keller et al.	222/137
6065645	May 2000	Sawhney et al.	222/459

ART-UNIT: 3754

PRIMARY-EXAMINER: Kaufman; Joseph A.

ABSTRACT:

A double-barreled syringe is provided which includes a mixing tip which is detachable after the tip is locked to the syringe body, so that the tip may be replaced by a locking cap. Locking occurs when a neck extending from the body between two shoulders is inserted into a bore in the tip (or, alternatively, the cap) and the tip is rotated so that two symmetrically opposed tabs attached to the tip are each received within a recess determined by a shoulder and a locking rib attached to the shoulder, and two diametrically opposed detents extending from the neck are each received within a recess in the bore surface.

14 Claims, 23 Drawing figures

Exemplary Claim Number: 1
Number of Drawing Sheets: 7

BRIEF SUMMARY:

1 BACKGROUND OF INVENTION

2 1. Field of the Invention

3 The present invention relates to multiple-barreled devices for mixing together and dispensing viscous substances. More particularly, the invention relates to a double-barreled syringe having a double-barreled plunger of unitary construction for dispensing an admixture formed when two gels stored in the barrels are simultaneously discharged into a mixing tip having a five section static mixing element. The tip, which interlocks with the syringe body, is detachable and may be replaced by a locking closure cap to prevent leakage when the syringe is not in use. The locking closure cap preferably has a liner which mitigates undesirable leakage during transport and storage.

4 2. Description of the Related Art

5 Devices for mixing and dispensing a viscous fluid having separately stored constituents wherein a mixing, portion is detachably connected to a storage portion are known in the art. U.S. Pat. No. 5,413,253 to C. Simmen discloses a static mixer for connection to a cartridge having at least two chambers containing different materials. The mixer is connected to the cartridge by inserting hollow circular make prongs and arcuate positioning keys of a center plug within corresponding female outlets in the cartridge. The plug is rotatably mounted within the collar of a sleeve. The mixer is locked to the cartridge by rotating the collar until opposed tabs on the sleeve engage with locking arms on the dispensing end of the cartridge.

6 U.S. Pat. No. 4.538,920 to G.E. Drake discloses a double-barreled syringe for mixing and dispensing a two-component material such as a resin and its hardener. Both a mixing tip and a static mixing element located within the tip bore are flexibly rotationally aligned with the syringe body so that the first blade of the mixing element is generally perpendicular to the plane of contiguity between the two component streams exiting a syringe body outlet. The mixing tip is connected to the body by centering the tip inlet over the body outlet while aligning the tip so that it can be pushed between opposed bayonet locking tabs, each having a prong and a stop surface, and then rotating the tip so that opposed ramps on the tip inlet end are wedged between the prongs, and a stop surface proximate to each ramp engages a tab stop surface.

7 Although either of these devices enables the storage and mixing portions to be connected and then detached multiple times, both are so complex as to be unsuitable for mass production of inexpensive, throwaway dispensers. What is needed is a device which on demand can thoroughly mix two-component viscous materials and dispense a desired amount of the admixture, which will not leak when set aside, and which can be mass produced at relatively little cost.

8 OBJECTS OF THE INVENTION

9 Accordingly, it is an object of the present invention to provide a simple, reliable and convenient device which simultaneously dispenses equal amounts of two well mixed viscous materials as an admixture.

10 Another object of the invention is to provide a device which can be repetitively used to dispense desired amounts of an admixture.

11 A further object of the invention is to provide a device having a storage portion and a mixing-dispensing portion which repetitively can be easily connected and then detached, wherein the storage portion does not leak during

storage and transport thereof.

12 A still further object of the invention is to provide a device that is inexpensive to manufacture.

13 Other objects of the invention will become evident when the following description is considered with the accompanying drawing figures. In the figures and description, numerals indicate the various features of the invention, like numerals referring to like features throughout both the drawings and the descriptions.

14 SUMMARY OF INVENTION

15 These and other objects are achieved by the present invention which provides a double-barreled syringe wherein one barrel contains a hydrogen peroxide water-based gel formulation used for teeth whitening, and the other contains a gel formulation including compounds that will accelerate the release of oxygen from the first formulation and consequently increase the reaction rate of the teeth whitening process. The syringe dispenses an admixture formed when the two formulations are simultaneously discharged into a mixing tip having a static mixing element. The tip, which is in locking connection with the syringe body, is replaced by a locking closure cap to prevent leakage when the syringe is not in use.

16 The syringe body includes a double-barrel assembly having juxtaposed first and second barrels having a common length and a generally cylindrical bore of a common diameter. Each barrel is bounded at a discharge end by first and second shoulders, respectively, with each shoulder having a generally planar surface. The surfaces are coplanar and contiguous. A generally cylindrical neck extends from and is symmetrically disposed between the shoulders. The neck includes first and second outlet passages. Each barrel at its opposite (plunger) end closely receives a piston within its bore. An arcuately-shaped finger-grip circumscribes the contiguous plunger ends of the barrels.

17 The syringe body further includes a double-plunger assembly having juxtaposed first and second plungers of a common length. Each plunger extends at a proximal end in an end-piece rigidly attached to one of the pistons, and is rigidly attached at a distal end to a thumb-rest common to the plungers.

18 Alternatively, each plunger has a seal formed integrally therewith at a distal end thereof. The seal preferably comprises a flare having a wall thickness which is sufficiently thin as to flexibly conform to the bore within which it is contained and thus seal the plunger upon which it is formed with respect to the bore.

19 Further, according to the preferred embodiment of the present invention an alignment ring is formed proximate the distal end of each plunger. The alignment ring is formed proximal of the seal. The alignment ring enhances alignment of the seal with respect to the barrel within which the seal is disposed. The alignment ring is coupled comparatively flexibly to the shaft of the plunger and the alignment ring is coupled comparatively rigidly to the seal, so as to allow the combination of the alignment ring and the seal to move together as a unit with respect to the shaft while also causing the alignment ring and the seal to remain comparatively fixed in position with respect to one another. In this manner, the alignment ring and the seal remain aligned with respect to the bore within which they are disposed regardless of bending of the shaft of the plunger which may occur during use.

20 According to the preferred embodiment of the present invention, the alignment ring is attached to the shaft by a first neck and the seal is attached to the alignment ring by a second neck. The first neck has a smaller diameter than the second neck so as to facilitate movement of the combination of the alignment ring and the seal relative to the shaft, while maintaining desired relative alignment of the alignment ring with respect to the seal. Thus, the combination

of the alignment ring and the seal tends to move as a unit with respect to the shaft (which may bend independently of the alignment ring and the seal).

21 The syringe body further includes a first mating assembly having diametrically opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to the neck and rigidly attached, respectively, to the first and second shoulders. Each rib has a plurality of generally planar locking faces generally parallel to and at a common predetermined distance from the neighboring shoulder surface.

22 The syringe further includes a generally conical mixing tip having an inlet end and a discharge end and a bore therethrough. The bore has a generally cylindrical portion at the inlet end and extends in a conically tapered portion toward the discharge end. The cylindrical bore portion is determined by a circumferential surface adapted to closely receive the body neck. A four section static mixing element is closely received and wedged within the bore tapered portion. The mixing tip has at the inlet end a second mating assembly having opposed generally planar, arcuate first and second locking tabs of a common predetermined thickness slightly less than the distance between the rib locking faces of the first mating assembly and the neighboring shoulder. Each tab has at least one edge beveled at a common predetermined angle. The tabs are symmetrically disposed with respect to the cylindrical bore portion. The bore circumferential surface includes diametrically opposed first and second detent recesses and first and second ramps which are contiguous at a proximal end, respectively, to the recesses.

23 Alternatively, a five section static mixing element is received and wedged within the bore tapered portion. It is believed that the use of a five section static mixing element will provide approximately 50% better mixing than the four section static mixing element. Those skilled in the art will appreciate that additional sections of the static mixing element will provide further enhanced mixing and may therefore be desirable.

24 According to the preferred embodiment of the present invention, each section of the static mixing element comprises a single turn screw. Each screw is clocked, i.e., configured so as to be right or left handed, opposite that of each adjacent screw and is oriented, with respect to the leading and trailing edges thereof, at 90% with respect to each adjacent screw. Thus, as the two viscous materials flow from one screw to the next screw, the viscous materials are split into two portions, so as to effect desired mixing thereof. The screws are disposed upon a common shaft. The screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

25 The first and second mating assemblies are conjoined when the neck is inserted into the cylindrical bore portion in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration. The assemblies interlock when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess. Concurrently, each tab is closely received between one of the pluralities of rib locking faces and a shoulder. The mating assemblies are detachable when the mixing tip is rotated in the opposite direction until the neck and cylindrical bore portion are in the engaged configuration.

26 Optionally, a locking closure cap is utilized in place of the mixing tip so as to better mitigate leakage during shipping. The locking closure cap attaches to the body in the same manner as the mixing tip. Preferably, the locking closure cap comprises a locking closure cap liner formed of a comparatively resilient material which provides an enhanced seal between the locking closure cap and the body. The locking closure cap liner preferably comprises a groove formed therein and configured so as to receive a partition formed within the neck of the body.

DRAWING DESCRIPTION:

A more complete understanding of the present invention and other objects, aspects and advantages thereof will be gained from a consideration of the following description of the preferred embodiment read in conjunction with the accompanying drawings provided herein.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a double-barreled syringe according to the invention, including a double-plunger assembly, two pistons, a double-barrel assembly, a static mixing element, a detachable locking mixing tip, and alternatively, a detachable locking cap;

FIG. 2 is a discharge end perspective view of the FIG. 1 double-barrel assembly, including two shoulders, a neck with two outlet passages, and a mating assembly with two diametrically opposed detents and two symmetrically disposed locking ribs for engaging and interlocking with the mixing tip or cap;

FIG. 3 is an inlet end perspective view of the FIG. 1 mixing tip, including a mating assembly, having two locking tabs, which engages and interlocks with the FIG. 2 mating assembly;

FIG. 4A is a combined exploded perspective and partial sectional view of the FIGS. 2 and 3 mating assemblies before engagement:

FIG. 4B is a combined perspective and partial sectional view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 4C is a combined perspective and partial sectional view of the FIGS. 2 and 3 mating assemblies after interlocking;

FIG. 5A is a perspective view of the FIGS. 2 and 3 mating assemblies before engagement;

FIG. 5B is a perspective view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 5C is a perspective view of the FIGS. 2 and 3 mating assemblies after interlocking;

FIG. 6A is a transverse sectional view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 6B is a transverse sectional view of the FIGS. 2 and 3 mating assemblies after interlocking;

FIG. 6C is a cross-sectional view of the FIG. 6B mating assemblies taken along offset line 6C--6C, showing each locking tab disposed within a recess determined by a FIG. 2 shoulder and locking rib;

FIG. 7 is a horizontal cross-sectional view of the FIG. 2 discharge end and FIG. 3 inlet end when the mixing tip is locked to the double-barrel assembly;

FIG. 8 is a cross-sectional view orthogonal to FIG. 7;

FIG. 9 is a perspective view of a unitary double-barreled plunger having integrally formed seals at the distal ends thereof.

FIG. 10 is an enlarged side view of one of the distal ends of the double-barreled plunger of FIG. 9, showing the seal;

FIG. 11 is a cross sectional perspective view of the distal end of the plunger of

FIG. 10;

FIG. 12 is a horizontal cross-sectional view of an alternative configuration of the mixing tip, wherein a five element mixer is used instead of the four element mixer of FIGS. 7 and 8;

FIG. 13 is a cross-sectional view orthogonal to FIG. 12;

FIG. 14 is an enlarged side view of the five section mixing element of FIGS. 12 and 13;

FIG. 15 is a perspective view of a locking closure cap showing the locking closure cap liner thereof exploded therefrom;

FIG. 16 is an enlarged perspective view of the locking closure cap of FIG. 15, showing the locking closure cap liner installed therein; and

FIG. 17 is a discharge end perspective view of the double-barrel assembly, including two shoulders, a neck with two outlet passages separated by a straight partition, and a mating assembly with two diametrically opposed detents and two symmetrically disposed locking ribs for engaging and interlocking with the mixing tip or cap.

DETAILED DESCRIPTION:

1 DESCRIPTION OF THE PREFERRED EMBODIMENT

2 While the present invention is open to various modifications and alternative constructions, the preferred embodiment shown in the drawings will be described herein in detail. It is to be understood, however, there is no intention to limit the invention to the particular form disclosed. On the contrary, it is intended that the invention cover all modifications, equivalences and alternative constructions falling within the spirit and scope of the invention as expressed in the appended claims.

3 The invention relates to an article of manufacture which is primarily intended for storing and dispensing gels which are components of an admixture and which need to be kept separate until the admixture is formed. However, the invention is not limited to particular types of material to be stored and dispensed, and can be used for storing and dispensing any material that can be placed within a syringe barrel and effectively admixed by a static mixing tip.

4 Where used herein, the word "attached" means that the two parts referred to (e.g., a locking rib and a shoulder or a plunger end-piece and a piston) are either molded in a single piece, or are glued or force-fitted together. However, other forms of attachment may be suitable, consistent with simplicity of manufacture and reliability of operation. Where used herein, the word "connected" means that the two parts referred to (viz., the two mating assemblies) can be easily separated after being joined together in an interlocking combination.

5 Referring to FIGS. 1 and 2, a syringe body 10 includes a double-barrel assembly 12 having juxtaposed first and second generally cylindrical barrels 14L, 14R having a common length and a generally cylindrical bore 16L, 16R, respectively, of a common diameter determining storage compartments 15L (not shown), 15R (not shown). Barrels 14L, 14R are bounded at a first (discharge) end 18L, 18R, respectively, by first and second shoulders 20L, 20R, respectively. The shoulders have generally planar surfaces 21L, 21R, respectively, which are coplanar and contiguous. A generally cylindrical neck 22 extends from and is symmetrically disposed between the shoulders. As shown in FIG. 2, neck 22 includes first and second outlet passages 24L, 24R, divided by a partition 26. As best shown in FIG. 7, passages 24L, 24R are in fluid communication, respectively, with barrels 14L, 14R. Barrels 14L, 14R are open at an opposite (plunger) end 28L, 28R, respectively, which closely receives a piston 30L, 30R,

respectively. Barrel ends 28L, 28R are circumscribed by and rigidly attached to an arcuately-shaped finger-grip 32.

6 The syringe body 10 further includes a double-plunger assembly 36 having juxtaposed generally cylindrical first and second plungers 38L, 38R of a common length. Each plunger extends at an end 40L, 40R proximal to a piston in an end-piece 42L. 42R rigidly attached to the piston 30L. 30R, respectively. The plungers are attached at their distal end 44L, 44R to a disc-shaped thumb-rest 46 so that when the thumb-rest is depressed the plungers move forward in tandem, and the attached pistons move in tandem within the barrels.

7 Still referring to FIG. 2, syringe body 10 further includes a first mating assembly 50 having diametrically opposed first and second detents 52, 54 extending outwardly from neck 22, and opposed first and second locking ribs 56L, 56R symmetrically disposed with respect to neck 22. Ribs 56L, 56R each have a first (stand-off) portion 57L, 57R, respectively, generally parallel to the shoulders 20L, 20R, respectively, and generally orthogonal to a second (bracket) portion 58L, 58R (not shown), respectively, rigidly attached, respectively, to shoulders 20L, 20R. Rib stand-off portions 57L, 57R each have two generally planar locking faces 59L, 60L, and 59R (not shown), 60R (not shown), respectively, which are generally parallel to and at a common distance from the neighboring shoulder surface 21L, 21R, respectively, thus determining symmetrical recesses 62L, 62R (not shown), respectively. Preferably, double-barrel assembly 12, including neck 22, and mating assembly 50 are fabricated as a unit from a polymerized alkene such as polypropylene by means of an injection molding process.

8 Referring to FIGS. 1 and 3, a generally conical mixing tip 70 includes an inlet end 72 and a discharge end 74 and a bore 76 therethrough. As best shown in FIG. 3, bore 76 has a generally cylindrical portion 78 proximate to inlet end 72 and extends in a conically tapered portion 80 (not shown) toward the discharge end 74. Cylindrical bore portion 78 is determined by a circumferential surface 78S adapted to closely receive the neck 22. As best shown in FIGS. 7 and 8, a static mixing element 82 is closely received and wedged within the tapered bore portion 80. The static mixing element 82 comprises a four section static mixing element. That is, the mixing element 82 is comprised of four separate single turn screws. Mixing element 82 is inserted in a random azimuthal orientation within bore portion 80 and so is not disposed in a predetermined orientation with respect to partition 26 and outlet passages 24L, 24R when mixing tip 70 is attached to double-barrel assembly 12. As further shown in FIGS. 7 and 8, when tip 70 and assembly 12 are attached, proximate end 82P of mixing element 82 and neck 22 are separated by a gap 83. Mixing tip 70 further includes an indented surface portion 84 to facilitate a person holding the tip between the thumb and fingers to rotate the tip.

9 Still referring to FIG. 3, the inlet end 72 of mixing tip 70 includes a second mating assembly 90 having opposed generally planar arcuately-shaped first and second locking tabs 92, 94 of a common predetermined thickness slightly less than the common width of recesses 62L, 62R. Tabs 92, 94 are symmetrically disposed with respect to cylindrical bore portion 78 and have edges 93A (not shown), 93B (not shown) and 95A, 95B, respectively, which are each beveled at an angle of about 8 degrees. Tabs 92, 94 are rigidly attached, respectively, to structural ribs 98, 100 disposed symmetrically with respect to bore portion 78, and extending in generally oval-shaped collar portions 102, 104, respectively. The two collar portions partially circumscribe inlet end 72 and extend so that tab 92 is rigidly attached at an interior edge 92E (not shown) to collar portion 104, and tab 94 is rigidly attached at an interior edge 94E to collar portion 102. Surface 78S includes diametrically opposed first and second detent recesses 110, 112 and a plurality of corrugations 114. As shown in FIGS. 4A, 4B, 6A and 6B, recesses 110, 112 are each contiguous to first and second ramps 116, 118, respectively, which are generally planar sloping portions of the surface 78S. As shown in FIGS. 4B and 6A, when neck 22 is inserted within bore portion 78, each detent 52, 54 contacts a ramp 116, 118, respectively, at a ramp end 120, 122, respectively, distal to recess 110, 112, respectively. As

shown in FIGS. 4C and 6B, when mixing tip 70 is rotated counterclockwise with respect to double-barrel assembly 12, each detent 52, 54 traverses the contacting ramp to the proximal ramp end 124, 126, and is received within the recess. Preferably, mixing tip 70 and associated mating assembly 90 are fabricated as a unit from a polymerized alkene such as polypropylene by means of an injection molding process. As shown in FIG. 1, mixing tip 70 may be replaced by a closure cap 130 having a mating assembly identical to mating assembly 90 so that cap 130 is interchangeable with mixing tip 70.

10 FIGS. 4A and 5A show the proper relative orientation between mating assemblies 50 and 90 so that neck 22 can be inserted into bore portion 78. FIGS. 4B and 6A show the mating assemblies engaged but not yet interlocked. FIG. 5B shows the disposition in the engaged position of collar portion 102 with respect to locking ribs 56L, 56R of mating assembly 50. In FIGS. 4B and 6A, arrows 120, 121 show the (counterclockwise) rotational direction for interlocking. FIGS. 4A and 4B show rib stand-off portions 57L and 57R with respective locking faces 59L, 60L and 59R, 60R. FIGS. 4B and 6A further show the respective disposition of locking tabs 92, 94 of mating assembly 90 and rib stand-off portions 57L, 57R of mating assembly 50 before interlocking. FIGS. 4C and 6B show the respective disposition of locking tabs 92, 94 and rib stand-off portions 57L, 57R after interlocking when tabs 92,94 have been closely received within recesses 62L, 62R, respectively, and detents 52, 54 received within recesses 110, 112, respectively. Tab insertion and removal are facilitate by beveled edges 93A, 93B of tab 92 and beveled edges 95A, 95B of tab 94. FIG. 5C shows the disposition in the interlocked position of collar portion 102 with respect to locking ribs 56L, 56R. FIGS. 6 and 7 show locking tabs 92, 94 received within recesses 62L 62R, respectively, determined, respectively, by shoulders 20L, 20R and rib stand-off portions 57L, 57R with locking faces 59L, 60L and 59R, 60R. As best shown in FIG. 7, locking tabs 92, 94, when received within recesses 62L, 62R, contact locking faces 59L, 60L and 59R, 60R, respectively. FIG. 8 shows detents 52, 54 in relation, respectively, to recesses 110, 112 and to collar portions 102, 104.

11 After dispensing a desired amount of admixture, a user typically would detach the mixing tip 70 from the double-barrel assembly 12 by rotating the tip clockwise until detents 52, 54 reach ramp distal ends 120, 122, at which position locking tabs 92, 94 are disengaged from recesses 62L, 62R, and then pulling apart the mixing tip and double-barrel assembly. The corrugation in surface 78S contiguous to each ramp distal end acts as a stop for the detent, thus preventing over-rotation and ensuring that mating assemblies 50 and 90 return to the engaged position. The closure cap 130 may then be connected to the syringe body 10 by using the same engagement and locking procedure as used for the tip.

12 Preferably, the double-barrel assembly 12 and attached mating assembly 50, double-plunger assembly 36, mixing tip 70 and attached mating assembly 90, and closure cap 130 are fabricated from a polymerized alkene such as polypropylene. Preferably, the length between thumb-rest 46 and discharge end 74 of mixing tip 70 is about 6.75 inches when plungers 38L, 38R are fully retracted. Preferably, the combined width of juxtaposed barrels 14L, 14R is about 0.65 inch.

13 Referring now to FIGS. 9-11, the plunger alternatively comprises a unitary construction double-barreled plunger 336 having sealing tips 200L and 200R formed integrally with shafts 210L and 210R of the plungers 338L and 338R thereof. In this manner, the need for separate sealing tips, such as those of pistons 30L and 30R of FIG. 1, is eliminated. By eliminating such separate sealing tips, both the materials and assembly costs associated with the plunger assembly 336 are reduced.

14 With particular reference to FIGS. 10 and 11, the right sealing tip 200R comprises a shaft 210R having a first neck 212 attaching the shaft to 210R to an alignment ring 204 and a second neck 208 attaching the alignment ring 204 to a seal 202R. Although only the distal end of one plunger 338R is shown in FIGS. 10 and 11, it will be appreciated that both plungers 338L and 338R are

substantially identical.

15 The shaft 210R has a diameter. Dimension A, which is substantially greater than a diameter, Dimension B of the first neck 212. The diameter of the shaft 210R, Dimension A, is somewhat less than the diameter of the cylindrical bore 16R (FIG. 1) within which the shaft 210R is disposed, so as to facilitate easy movement of the shaft 210R within the cylindrical bore 16R. The alignment ring 204 comprises a first portion 214 having a diameter, Dimension C, which is approximately equal to the diameter, Dimension A, of the shaft 210R. The alignment ring 204 also has a second portion 216 which has a diameter, Dimension D, which is greater than the diameter, Dimension C, of the first portion 204 thereof. The diameter, Dimension D, of the second portion 216 of the alignment ring 204 is approximately equal to the diameter of the cylindrical bore 16R within which the plunger 338R is slidably disposed, so as to provide a close fit therewith. The second portion 216 preferably defines a radiused or rounded surface where it contacts the cylindrical bore 16R.

16 Second neck 208 has a dianeter, Dimension E, which is less than the diameter, Dimension C, of the first portion 214 of the alignment ring 204 and which is greater than the diameter, Dimension B, of the first neck 212.

17 The seal 202R has a first portion 220 which has a diameter, Dimension F, which is approximately equal to the diameter, Dimension D, of the second portion 216 of the alignment ring 204 (and which is thus approximately equal to the diameter of the cylindrical bore 16R). The seal 202R also has a second portion 206 which has a diameter, Dimension G, which is substantially greater than the diameter, Dimension F, of the first section 220 of the seal 202R. The second section 206 of the seal 202R is defined by a flare which is comprised of a relatively thin, and consequently comparatively flexible, portion of the seal 202R, and which therefore conforms generally in diameter to the cylindrical bore 16R. In this manner, the second portion 206 of the seal 202R provides a seal between the plunger 38Y and the first bore 16R within which the plunger 338R is disposed.

18 The alignment ring 204 functions so as to maintain desired alignment of the seal 202R with respect to the cylindrical bore 16R, particularly during use, e.g., dispensing of fluid, of the syringe. During use of the double-barreled syringe, the shaft 210R tends to flex or bow as the thumb rest 46 is pushed so as to force viscous material from the cylindrical bore 16R. The alignment ring 204 mitigates misalignment of the seal 202R and consequent undesirable leakage of viscous material thereby. The alignment ring 204, in combination with the neck 208 and the seal 202R, define a spool-like member which is substantially more resistant to misalignment within the cylindrical bore 16L than is the seal 202R alone.

19 The first neck 212, which has a substantially smaller diameter, Dimension B, than the diameter, Dimension E, of the second neck 208, permits some desired movement of the shaft 210R of the plunger 338R, with respect to the combination of the alignment ring 204 and the seal 202R (which are rigidly attached to one another) such that bending of the shaft 210R does not effect substantial misalignment of the seal 202R.

20 The diameter, Dimension C, of the first section 214 of the alignment ring 204 is substantially less than the diameter of the cylindrical bore 16R, and the second section 216 of the alignment ring 204 has a diameter. Dimension D, approximately equal to that of the diameter of the cylindrical bore 16R, so as to provide a desired amount of friction between the alignment ring 204 and the cylindrical bore 16R. The radiused or rounded contact surface of the second section 216 also contributes to providing the desired amount of friction between the alignment ring 204 and the cylindrical bore 16R. According to the preferred embodiment of the present invention, Dimension A is approximately 0.241 inch. Dimension B is approximately 0.129 inch, Dimension C is approximately 0.238 inch, Dimension D is approximately 0.250 inch, Dimension E is approximately 0.165, Dimension F is approximately 0.250 inch and Dimension

G. is approximately 0.260 inch. The unitary construction double-barreled plunger 336 is preferably fabricated from a polymerized alkene such as polypropylene. Referring now to FIGS. 12-14, the mixing tip 70A alternatively comprises a five section static mixing element 82A. The five section static mixing element 82A comprises first 240A, second 240B, third 240C, fourth 240D and fifth 240E sections. Each section 240A-240E of the static mixing element 82A preferably comprises a single turn screw formed upon a common shaft 242 (best shown in FIG. 14) such that each section has a different clock sense, i.e., rotates in a different direction, from each adjacent section. That is, if the screw of a given section 240A-240E is clockwise, then any immediately adjacent section(s) will have a counter clockwise sense. Further, the leading edge of each screw is oriented at approximately 90 degrees with respect to the trailing edge of each preceding screw, such that as fluid flows from one screw to another, the fluid is cut approximately in half, so as to effect desired mixing thereof. The five section static mixing element 82A is preferably fabricated from a polymerized alkene such as polypropylene.

21 Referring now to FIGS. 15 and 16, a locking closure cap 130 preferably comprises a locking closure cap liner 260 for enhancing the seal between the locking closure cap 130 and the neck 22 so as to prevent undesirable leakage of fluids from the first 14L and second 14R cylindrical barrels.

22 According to the preferred embodiment of the present invention, the locking closure cap liner 260 comprises a base 262 and two outwardly extending protrusions 264 and 266 which define a groove 268 therebetween. The groove 268 is configured so as to receive a generally planar partition 26A of the neck 22, as shown in FIG. 17. The two protrusions fit tightly within the two outlet passages 24L and 24R so as to effect desired sealing thereof. The base 262 provides further sealing as it is compressed against the neck 22 by the locking closure cap 130. The base 262 of the locking closure cap 130 is preferably compressed by approximately 0.008 inch when the locking closure cap 130 is attached to the syringe body 10.

23 The locking closure liner is preferably fabricated from polyolefin elastomer, preferably ENGAGE 8401 (ENGAGE is a federally registered trademark of Dupont Dow Elastomers). The locking closure cap is preferably fabricated form a polymerized alkene, such as polypropylene.

24 The locking closure cap liner 260 is preferably installed within the locking closure cap by inserting the two outwardly extending protrusions 264 and 266 into the neck 22 such that the partition 26A is received within the locking closure cap liner 260. Then, the locking closure cap 130 is attached to the syringe body 10 in the same manner that the mixing tip 70 is attached thereto. The partition 26A prevents rotation of the locking closure cap liner 260 as the locking closure cap 130 is rotated into the individual position thereof.

25 All of the polypropylene components of the present invention are preferably comprised of Polymerland 3320 AP polypropylene.

26 It is understood that the exemplary double-barreled syringe described herein and shown in the drawings represents only a presently preferred embodiment of the invention. Indeed, various modifications and additions may be made to such embodiment without departing from the spirit and scope of the invention. For example, the unitary construction plunger may alternatively comprise a plurality of alignment rings. Further, various different configurations of the locking closure cap liner are contemplated. Further, various numbers and configurations of the individual sections of the static mixing element are contemplated.

27 Thus, these and other modifications and additions may be obvious to those skilled in the art and may be implemented to adapt the present invention for use in a variety of different applications.

CLAIMS:

What is claimed is:

1. A syringe for dispensing two viscous materials as an admixture, comprising:

an integrally molded housing having a first and a second barrel that are symmetrical and fixedly opposed along a center line, the barrels are bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface and is coplanar with the other planar surface, a generally cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels, and a generally flat gripping member disposed at a proximal end of the housing;

a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached to said first and second shoulders, wherein said first mating assembly is configured to receive one of a mixing tip and a locking closure cap;

wherein said mixing tip has an inlet and an outlet, a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck;

wherein the mixing tip further includes a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, the two mating assemblies conjoining when the neck is inserted into the mixing tip bore in a relative orientation, and wherein the two mating assemblies interlock when the mixing tip rotates in a first direction and the locking tabs slide under the first and the second locking ribs until a stop is achieved, the two mating assemblies are detachable when the mixing tip is rotated in an opposite direction; and

wherein the mixing tip further including a static mixing element having a plurality of intertwined sections disposed within the cylindrical bore for mixing the two viscous materials as the two viscous materials are dispensed from the first and the second barrels.

2. The syringe of claim 1, wherein the intertwined sections comprise a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

3. The syringe of claim 2, wherein the screws are disposed upon a common shaft.

4. The syringe of claim 2, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

5. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof.

6. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having an alignment ring formed proximate a distal end thereof and a seal formed distal of the alignment ring, each alignment ring enhancing alignment of a seal with respect to the one of the barrels.

7. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring coupled comparatively

flexibly to the shaft of the plunger and the alignment ring coupled comparatively rigidly to the seal.

8. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring attached to the shaft by a first neck and the seal attached to the alignment ring by a second neck, the first neck having a smaller diameter than the second neck to facilitate movement of the alignment ring and the seal relative to the shaft.

9. The syringe of claim 1, further comprising a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

10. The syringe of claim 9, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the partition.

11. A syringe for mixing and administering a first and a second content, said syringe comprising:

an integrally molded body portion with two symmetrical barrels contiguously attached along a center contact line, each barrel having distal and proximal ends; said distal end of each barrel is configured with a generally planar shoulder and with an attached locking rib for gripping a mixer, said proximal end of each barrel includes a gripping member for improved gripping and an inlet for receiving a plunger, wherein each locking rib includes a body wall member for registering said mixer;

an outlet neck symmetrically disposed along the center contact line and equally spaced between the locking ribs on the shoulders; said outlet neck is in fluid communication with the two barrels and is configured to snugly fit into a bore on the mixer;

the mixer includes a mating assembly, wherein said mating assembly further includes a pair of mixer wall members and a pair of locking tabs, wherein said pair of mixer wall members are configured to abut with a corresponding pair of body wall members on the locking ribs to thereby register said mixer, and wherein said locking tabs are contiguous with said mixer wall members and are configured to frictionally engage the underside of said locking ribs; and

wherein said mixer further includes a series of intertwined screws in frictional engagement with said bore.

12. The syringe of claim 11, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto, such that as the two viscous materials flow from one screw to the next screw the

viscous materials are split into two portions to effect mixing thereof.

13. The syringe of claim 12, wherein the screws are disposed upon a common shaft.

14. The syringe of claim 12, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery; R. Eric	Monterey	MA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Montgomeory; R. Eric	Monterey	MA			04
Idex Dental Sciences, Inc.	Monterey	MA			02

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PARENT-CASE:
RELATED U.S. APPLICATIONS The present application is a continuation of U.S. application Ser. No. 08/719,569, filed on Sep. 25, 1996, now U.S. Pat. No. 5,922,307 which claims priority from Provisional Application Ser. No. 60/004,258, filed Sep. 25, 1995, both of which are hereby incorporated herein by reference.

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PRIOR-ART-DISCLOSED:

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Search Selected Search ALL

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ART-UNIT: 174

PRIMARY-EXAMINER: Anthony; Joseph D.

ABSTRACT:

The present invention relates to improved dental compositions and methods for bleaching teeth. More specifically, this invention is directed towards hydrogen peroxide-containing compounds that are maintained at a substantially constant pH range of 6.0-10.0 during the tooth-bleaching procedure in the presence of a calcium chelating agent.

20 Claims, 0 Drawing figures
Exemplary Claim Number: 1

BRIEF SUMMARY:

1 TECHNICAL FIELD

2 The present invention relates to improved dental bleaching compositions and methods for bleaching teeth.

3 BACKGROUND ART

4 White teeth have long been considered cosmetically desirable. Unfortunately, teeth become almost invariably discolored in the absence of intervention. The tooth structures which are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Tooth enamel is predominantly formed from inorganic material, mostly in the form of hydroxyapatite crystals and further contains approximately 5% organic material primarily in the form of collagen. In contrast, dentin is composed of about 20% protein including collagen, the balance consisting of inorganic material, predominantly hydroxyapatite crystals, similar to that found in enamel. The acquired pellicle is a proteinaceous layer on the surface of tooth enamel which reforms rapidly after an intensive tooth cleaning.

5 Staining of teeth results from extrinsic and/or intrinsic staining. Extrinsic staining of the acquired pellicle arises as a result of compounds such as tannins and polyphenolic compounds which become trapped in and tightly bound to the proteinaceous layer on the surface of the teeth. This type of staining can usually be removed by mechanical methods of tooth cleaning. In contrast, intrinsic staining occurs when staining compounds penetrate the enamel and even the dentin or arise from sources within the tooth. This type of staining is not amenable to mechanical methods of tooth cleaning and chemical methods are required.

6 Consequently, tooth-bleaching compositions generally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle; and (2) gels, pastes, or liquids that accomplish the tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is removed. In some cases, the mechanical process is supplemented by an auxiliary chemical process which may be oxidative or enzymatic.

7 The majority of professionally-monitored at-home tooth-bleaching compositions act by oxidation. These compositions are dispensed directly to a patient for use in a custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to 12 hours. The slow rate of bleaching is in large part, the consequence of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerine and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubes toward nerve endings in the tooth. This movement is enhanced by the carriers for the carbamide peroxide. In fact, it has been determined that glycerine, propylene glycol and polyethylene glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

8 Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization; penetration of the intact enamel and dentin by the bleaching agents, so as to reach the pulp chamber of a vital tooth thereby risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva with resulting leaching from the dental tray and subsequent digestion.

9 The stability of existing formulations of hydrogen peroxide-containing tooth-bleaching compositions in terms of shelf-life as well as over the period of use in the mouth, depends, in general, on an acidic pH. The hydrogen peroxide becomes markedly less stable as the pH increases. Indeed, Frysh, et al. Journal of Esthetic Dentistry Vol. 7, No. 3, pp. 130-133,1995) described the use of high concentration (35%) of hydrogen peroxide solutions at an initial alkaline pH, which was required to be formulated immediately before use and was administered in the form of a liquid to extracted teeth to achieve tooth bleaching. Phillips and Bowles (IADR Abstract J. Dent.res 75,1996) have demonstrated that hydrogen peroxide penetrates the enamel of extracted teeth less readily over a 15 minute period at pH 9.0 than at pH 4.5. Carbamide peroxide compositions have been formulated at a pH of 5.0-6.5 using hygroscopic carriers and maintaining a low water content. This type of formulation is problematic with regard to enhanced tooth sensitivity. On contact with saliva, the water content of the formulation increases, causing the carbamide to disassociate into urea and hydrogen peroxide and the pH to be decreased. In fact, the equilibrium pH of a 10% carbamide peroxide solution is approximately 3.45 and a typical commercially-available tooth-bleaching gel with 10% carbamide peroxide when combined with saliva in a 1:1 weight ratio has an initial pH of 5.6 and gradually decreases to pH 4.8 after 8 hours.

10 Thus, currently available tooth-bleaching compositions that rely on hydrogen peroxide as oxidizing agents, all release hydrogen peroxide from precursors at low pH levels despite the low rates of tooth-bleaching activity .

11 There is a need for a home use tooth-bleaching product that is stable, easy to use, and rapid-acting that utilizes reduced amounts of hydrogen peroxide and is capable of administration to a patient by means of a dental tray. There is a further need for a tooth-bleaching composition that may reduce hard and soft tissue irritation, tooth sensitivity, and bleaching composition ingestion to further increase patient compliance.

12 SUMMARY OF THE INVENTION

13 The invention satisfies the above needs. An embodiment of the invention includes a tooth-bleaching composition for contacting a tooth surface in a subject that includes a hydrogen peroxide-containing compound. Furthermore the composition includes a matrix for administering the hydrogen peroxide-containing compound to the tooth surface. The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent and a calcium chelating agent, wherein the pH of the tooth-bleaching composition during the bleaching process is substantially constant within a range of pH 6.0-10.

14 A further embodiment of the invention includes a dosage delivery unit for tooth bleaching, including a multi-chamber vessel wherein each chamber is responsive to an applied pressure from an external source, such that a mixture of reagents contained within a compartment including a hydrogen peroxide containing composition and a matrix, will be forced to exit the compartment through a mixing baffle in response to the externally applied pressure.

15 A further embodiment of the invention includes a method for bleaching teeth including preparing a composition as described above and administering the composition to the tooth surface.

16 DETAILED DESCRIPTION OF THE INVENTION

17 The present invention comprises compositions and methods for bleaching tooth enamel in situ which allow the use of reduced concentrations of hydrogen peroxide in tooth-bleaching compositions in order to achieve effective tooth bleaching in a contact time of less than one hour.

18 The tooth surface is defined here and in the claims as a portion of a tooth which is directly responsible for the stained appearance of said tooth. The term tooth surface generally means a tooth's acquired pellicle, plaque, enamel, and combinations thereof.

19 The matrix is defined here and in the claims as the gel, paste, or liquid in which the hydrogen peroxide containing compound is placed for administration to the subject.

20 The subject referred to here and in the claims is commonly a human subject but also includes domestic animals.

21 An important aspect of the present invention is the finding that the efficiency of the bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5, more particularly a pH in the range of 6-10, for example in a range of pH of 7-10, more particularly between 8.0 and 9.5, providing that the pH is maintained at a substantially constant range throughout the tooth-bleaching process and a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)

22 Suitable pH adjusting agents include, but are not limited to, sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, TRIS and triethanolamine.

23 Examples of calcium chelating agents include any of the calcium chelating agents known in the art. Examples include EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates. The use of citric acid, sodium acid pyrophosphate and disodium EDTA are shown in Table 1 and Table 2. The biological efficacy of sodium acid pyrophosphate is shown in Table 4. Without being bound to any particular theory, it is proposed that calcium precipitation in the form of calcium phosphates arise in the intercrystalline interstices of the tooth at elevated pHs and this gives rise to a blockage of movement of the peroxide into the tooth with a resulting negative effect on tooth bleaching. Calcium

chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth-bleaching effect.

24 The composition may also contain a stabilizing agent for removing from solution, metal ions that interfere with the action of the hydrogen peroxide. In certain formulations, a single component may act either as a calcium chelating agent or as a stabilizing agent or may serve both functions.

25 The ability to maintain a constant pH range above 5.5 throughout the period of tooth bleaching coupled with the inhibition of calcium precipitation that normally occurs at pH levels above 5.5, has resulted in a formulation that is suitable for use in the home and is capable of achieving detectable tooth bleaching in less than 30 minutes. Furthermore, multiple treatments (each treatment lasting no longer than 30 minutes) have been demonstrated to substantially whiten teeth (Example 5). In Example 5, 14 treatments using the inventive formulation, were administered for twenty minutes, twice a day over seven days. A mean .DELTA.E of 7.32 was observed denoting a substantial tooth-bleaching effect compared with a .DELTA.E of 4.73 using a prior art formulation for a period of time that was three times longer than that of the novel formulation.

26 According to the invention, additional agents having tooth-bleaching effect may be used to achieve detectable tooth bleaching in less than 30 minutes. For example, sodium percarbonate has been demonstrated to be very effective at tooth bleaching when maintained at a pH that is greater than 5.5, more preferably in the range of 7-10, more particularly 8-9.5 that includes a calcium chelating agent. This composition differs from carbamide peroxide in that there is no acidification of that solution that results upon its dissociation. Consequently, the reagent may be maintained at a constant elevated pH for an extended period of time without the necessity for adding buffering reagents beyond that naturally supplied in the saliva. Unlike carbamide peroxide, however, the percarbonate is prepared in a formulation that does not include glycerine and is only slowly permeated by water whereupon hydrogen peroxide is released. For this reason, it may be desirable, but is not essential, to prepare the percarbonate in a two-component composition, the two components being mixed before use so as to accelerate the tooth-bleaching effect (Examples 1 and 2). Formulations containing two components may be applied to the dental tray by squeezing a tube in much the same way as a single component. The mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer such that on squeezing the tube, material from each of the compartments is forced through the static mixer and are mixed together before emerging from a single exit in the tube.

27 The present invention has important health benefits that follow from shorter contact times of the tooth with hydrogen peroxide as well as the need for lower concentrations of peroxide to achieve a desired tooth-bleaching effect.

DETAILED DESCRIPTION:

1 EXAMPLE 1

2 Composition of a Stable Tooth-bleaching Formulation Suitable for Use in a One Component System

3 The formulations below utilized ultrapure components to avoid destabilization caused by metal ion contaminants. The chelating agent used here is one of disodium EDTA (1C), citric acid (1B), and sodium acid pyrophosphate (1F). The pH is modified using one of sodium hydroxide monohydrate (1A, 1B, 1C), ammonium hydroxide (1F,1G), Tris(hydroxymethyl) aminomethane (1D), and triethanolamine (1E). Carbopol is a high molecular weight crosslinked polyacrylic acid thickening agent. Hydrogen peroxide is used as the oxidizing agent.

TABLE 1

Example 1	A	B	C	D	E	F	G
Ingredient							
WEIGHT PERCENT							
Distilled Water	86.41	86.21	86.31	72.80	79.52	86.50	73.81
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02	0.02	0.02	0.03	0.02	0.30	0.40
Sodium stannate trihydrate	0.02	0.02	0.02	0.03	0.02	0.05	0.05
Citric acid	--	0.20	--	--	--	--	0.10
Calcium disodium EDTA	--	--	0.10	--	--	--	--
Sodium acid pyrophosphate	--	--	--	--	--	0.30	--
Hydrogen Peroxide 35%	10.30	10.30	10.30	17.14	17.14	8.60	17.14
Carbopol 974P (BF Goodrich)	2.50	2.50	2.50	5.00	--	3.00	5.00
Carbopol 934P (BF Goodrich)	--	--	--	--	2.00	--	--
Sodium Hydroxide Monohydrate	to pH 7.0	to pH 7.0	to pH 7.0	--	--	--	--
Ammonium hydroxide 28%	--	--	--	--	--	to pH 6.5	to pH 8.5
Tris(hydroxymethyl) aminomethane	--	--	--	to pH 8.0	--	--	--
Triethanolamine	--	--	--	--	to pH 6.0	--	--

Total	100	100	100	100	100	100	100
pH @ 25 deg. C.	7.0	7.0	7.0	8.0	6.0	6.5	8.5

4 The above formulations were prepared by dissolving the stabilizers 1-hydroxyethylidene-1,1-diphosphonic acid and the sodium stannate trihydrate in the distilled water using a Kynar-coated propeller-type agitator (reserving enough water, if necessary, to dissolve the neutralizer in the final step). The hydrogen peroxide was then added slowly to this mixture. The Carbopol 974P was then added to the distilled water/stabilizer/hydrogen peroxide mixture slowly while a vortex was formed with the agitator blade. This dispersion was then placed in a Kynar-coated vacuum double planetary mixer to which the pH adjusting agent was added slowly to affect neutralization of the Carbopol 974P and to adjust the final composition pH. The resulting composition was a transparent, viscous gel and was packaged in foil/plastic laminate tubes having a polyethylene product contact liner.

5 EXAMPLE 2

6 A Two Component Alkaline Tooth-bleaching Formulation

7 A hydrogen peroxide-releasing composition was formulated which utilized sodium percarbonate in an anhydrous gel, and was designed to be combined with a separate aqueous gel prior to use in order to dissolve the sodium percarbonate to form hydrogen peroxide and sodium carbonate. The pH of this composition, shown in Table 2, when combined in a volume ratio of 1 to 1, was 9.0. The chelating agents used here are EDTA and sodium acid pyrophosphate.

TABLE 2

EXAMPLE 2	PART A	PART B
INGREDIENT	WEIGHT PERCENT	
Distilled Water	--	95.20
Polyethylene glycol 400	83.00	--
Sodium percarbonate (powder)	12.00	--
EDTA	--	0.20
Sodium acid pyrophosphate	--	0.30
Carbopol 974P (BF Goodrich)	2.5	4.00
Sodium Hydroxide Monohydrate	--	to pH 7.0
Tris(hydroxymethyl)aminomethane	2.50	--
Total	100	100

8 The above composition parts were prepared as follows:

9 Part A

10 The Carbopol was dispersed in the polyethylene glycol using a propeller-type agitator with Kynar-coated product contact surfaces. The resulting dispersion was added to a Kynar-coated vacuum double planetary mixer (as in Example 1) and neutralized with the tris(hydroxymethyl)aminomethane under low shear mixing. To the resultant neutralized Carbopol gel, sodium percarbonate was added and dispersed until the composition was a homogenous white paste.

11 Part B

12 The Carbopol was added to the water (in which the EDTA and sodium acid pyrophosphate had already been dissolved) and agitated as above. The resulting dispersion was transferred to the Kynar-coated vacuum double planetary mixer and neutralized with the sodium hydroxide monohydrate under low shear mixing. The final gel was clear and viscous, with a pH of around 7.0.

13 EXAMPLE 3

14 Preparation of a Tooth-bleaching Formulation Having Acidic pH

15 In order to demonstrate the superior ability of the inventive hydrogen peroxide gel composition of Examples 1 and 2 to bleach teeth, a composition was prepared which was similar to that of Example 1E, except that the pH was adjusted to 4.5.

TABLE 3

INGREDIENT	PERCENT
Distilled water	79.82
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02
Sodium stannate trihydrate	0.02
Carbopol 974P	2.00
Hydrogen Peroxide 35%	17.14
Triethanolamine	1.00
TOTAL	100.00

16 The formulation was prepared as in Example 1, resulting in a transparent, viscous gel with a pH of approximately 4.5. The formulation is similar to 1E, the difference lying in the pH of the composition.

17 EXAMPLE 4

18 Assay to Determine Tooth Bleaching

19 Bovine incisors, which had been imbedded in an acrylic matrix such that the buccal surfaces presented themselves on the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, FeCl.sub.3, and Sarcina lutea, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer

(3 mm aperture, 8 exposure average, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as .DELTA.E. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

[(.DELTA.L).sup.2 +(.DELTA.a).sup.2 +(.DELTA.b).sup.2]=.DELTA.E

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	.DELTA.E
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

20 This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased .DELTA.E from 4.29 to 6.27.

21 The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in .DELTA.E in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

22 Opalescence is a commercial product which has been pH adjusted to pH 6.5 before

use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

23 EXAMPLE 5

24 In vivo Demonstration of Tooth Bleaching

25 Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

26 One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

27 The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

28 The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	.DELTA.E
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opal- es- cence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opal- es- cence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opal- es-	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

cence

29 The average .DELTA.E for the Example 1B group was 7.32, whereas the average .DELTA.E for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

CLAIMS:

I claim:

1. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount,

an aqueous matrix comprising

a calcium chelating agent,

a thickening agent, and

an alkaline pH adjusting agent,

wherein the mixture has a pH within a range of between approximately 6.0 and approximately 10.0 and wherein the mixture is packaged as a single component system.

2. A composition according to claim 1, wherein the water content is at least 75% by weight, based on the weight of the composition.

3. A composition according to claim 1, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

4. A composition according to claim 1, wherein the thickening agent is a high molecular weight crosslinked polyacrylic acid.

5. A composition according to claim 1, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

6. A composition according to claim 1, wherein the matrix also has a stabilizing agent selected from the group consisting of sodium stannate trihydrate, 1-Hydroxyethylidene-1,1-diphosphonic acid, and combinations thereof.

7. A composition according to claim 6, wherein the stabilizing agent may also act as a calcium chelating agent.

8. A composition according to claim 6, wherein the aqueous matrix has a water content of at least 70% by weight, based on the weight of the composition.

9. A composition according to claim 6, wherein the matrix is sufficiently pure in order to avoid peroxide destabilization by metal ion contaminants, so as to permit packaging as a one-component system.

10. A composition according to claim 6, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

11. A composition according to claim 6, wherein the thickening agent is a high

molecular weight crosslinked polyacrylic acid.

12. A composition according to claim 6, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

13. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising:

hydrogen peroxide,

an aqueous matrix comprising

a high molecular weight crosslinked polyacrylic acid in an amount between approximately 2.0% and approximately 5.0% by weight, based on the weight of the mixture,

an alkaline pH adjusting agent, and

sodium stannate trihydrate, 1-Hydroxyethylidene-1,1-diphosphonic acid, and combinations thereof, in an amount between approximately 0.02% and approximately 0.5% by weight, based on the weight of the mixture,

wherein the mixture has a pH within a range of between approximately 6.0 and approximately 10.0 and wherein the mixture is packaged as a single component system.

14. A composition according to claim 13, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

15. A composition according to claim 13, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

16. A composition according to claim 13, wherein the matrix also has

a concentration of a calcium chelating agent of between approximately 0.02% and approximately 0.4% by weight, based on the weight of the composition.

17. A composition according to claim 13, wherein the stabilizing agent may also act as a calcium chelating agent.

18. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount a thickening agent,

water,

a calcium chelating agent, and

an alkalizing agent,

wherein the tooth bleaching mixture has a pH within a range of between approximately 7.0 and approximately 10.0 and wherein the tooth bleaching mixture is a single component system.

19. The tooth bleaching mixture of claim 18 wherein the tooth bleaching mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

20. The tooth bleaching mixture of claim 18 wherein the tooth bleaching mixture has a pH of approximately 8.

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L1: Entry 51 of 852 File: USPT Nov 27, 2001

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DOCUMENT-IDENTIFIER: US 6322773 B1

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery; R. Eric	Monterey	MA	01245	

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Montgomery; R. Eric	Monterey	MA			04
Idex Dental Sciences, Inc.	Monterey	MA			02

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RELATED U.S. APPLICATION(S) The present application is a continuation of U.S. application Ser. No. 09/054,156, filed on Apr. 2, 1998, itself a divisional of U.S. application Ser. No. 08/719,569, filed on Sep. 25, 1996, which issued on Jul. 13, 1999 as U.S. Pat. No. 5,922,307, and which claims priority from Provisional Application Serial No. 60/004,258, filed Sep. 25, 1995, all of which are hereby incorporated herein by reference.

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PRIOR-ART-DISCLOSED:

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ART-UNIT: 164

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

The present invention relates to improved dental compositions and methods for bleaching teeth. More specifically, this invention is directed towards hydrogen peroxide-containing compounds that are maintained at a substantially constant pH range of 6.0-10.0 during the tooth-bleaching procedure in the presence of a calcium chelating agent.

20 Claims, 0 Drawing figures
Exemplary Claim Number: 1

BRIEF SUMMARY:

1 TECHNICAL FIELD

2 The present invention relates to improved dental bleaching compositions and methods for bleaching teeth.

3 BACKGROUND ART

4 White teeth have long been considered cosmetically desirable. Unfortunately, teeth become almost invariably discolored in the absence of intervention. The tooth structures which are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Tooth enamel is predominantly formed from inorganic material, mostly in the form of hydroxyapatite crystals and further contains approximately 5% organic material primarily in the form of collagen. In contrast, dentin is composed of about 20% protein including collagen, the balance consisting of inorganic material, predominantly hydroxyapatite crystals, similar to that found in enamel. The acquired pellicle is a proteinaceous layer on the surface of tooth enamel which reforms rapidly after an intensive tooth cleaning.

5 Staining of teeth results from extrinsic and/or intrinsic staining. Extrinsic staining of the acquired pellicle arises as a result of compounds such as tannins and polyphenolic compounds which become trapped in and tightly bound to the proteinaceous layer on the surface of the teeth. This type of staining can usually be removed by mechanical methods of tooth cleaning. In contrast, intrinsic staining occurs when staining compounds penetrate the enamel and even the dentin or arise from sources within the tooth. This type of staining is not amenable to mechanical methods of tooth cleaning and chemical methods are required.

6 Consequently, tooth-bleaching compositions generally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle; and (2) gels, pastes, or liquids that accomplish the tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is removed. In some cases, the mechanical process is supplemented by an auxiliary chemical process which may be oxidative or enzymatic.

7 The majority of professionally-monitored at-home tooth-bleaching compositions act by oxidation. These compositions are dispensed directly to a patient for use in a custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to

12 hours. The slow rate of bleaching is in large part, the consequence of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerine and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubes toward nerve endings in the tooth. This movement is enhanced by the carriers for the carbamide peroxide. In fact, it has been determined that glycerine, propylene glycol and polyethylene glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

8 Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization; penetration of the intact enamel and dentin by the bleaching agents, so as to reach the pulp chamber of a vital tooth thereby risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva with resulting leaching from the dental tray and subsequent digestion.

9 The stability of existing formulations of hydrogen peroxide-containing tooth-bleaching compositions in terms of shelf-life as well as over the period of use in the mouth, depends, in general, on an acidic pH. The hydrogen peroxide becomes markedly less stable as the pH increases. Indeed, Frysh, et al. (Journal of Esthetic Dentistry Vol. 7, No. 3, pp. 130-133, 1995) described the use of high concentration (35%) of hydrogen peroxide solutions at an initial alkaline pH, which was required to be formulated immediately before use and was administered in the form of a liquid to extracted teeth to achieve tooth bleaching. Phillips and Bowles (IADR Abstract J. Dent.res 75, 1996) have demonstrated that hydrogen peroxide penetrates the enamel of extracted teeth less readily over a 15 minute period at pH 9.0 than at pH 4.5. Carbamide peroxide compositions have been formulated at a pH of 5.0-6.5 using hygroscopic carriers and maintaining a low water content. This type of formulation is problematic with regard to enhanced tooth sensitivity. On contact with saliva, the water content of the formulation increases, causing the carbamide to disassociate into urea and hydrogen peroxide and the pH to be decreased. In fact, the equilibrium pH of a 10% carbamide peroxide solution is approximately 3.45 and a typical commercially-available tooth-bleaching gel with 10% carbamide peroxide when combined with saliva in a 1:1 weight ratio has an initial pH of 5.6 and gradually decreases to pH 4.8 after 8 hours.

10 Thus, currently available tooth-bleaching compositions that rely on hydrogen peroxide as oxidizing agents, all release hydrogen peroxide from precursors at low pH levels despite the low rates of tooth-bleaching activity.

11 There is a need for a home use tooth-bleaching product that is stable, easy to use, and rapid-acting that utilizes reduced amounts of hydrogen peroxide and is capable of administration to a patient by means of a dental tray. There is a further need for a tooth-bleaching composition that may reduce hard and soft tissue irritation, tooth sensitivity, and bleaching composition ingestion to further increase patient compliance.

12 SUMMARY OF THE INVENTION

13 The invention satisfies the above needs. An embodiment of the invention includes a tooth-bleaching composition for contacting a tooth surface in a subject that includes a hydrogen peroxide-containing compound. Furthermore the composition includes a matrix for administering the hydrogen peroxide-containing compound to the tooth surface. The matrix comprises a

thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent and a calcium chelating agent, wherein the pH of the tooth-bleaching composition during the bleaching process is substantially constant within a range of pH 6.0-10.

14 A further embodiment of the invention includes a dosage delivery unit for tooth bleaching, including a multi-chamber vessel wherein each chamber is responsive to an applied pressure from an external source, such that a mixture of reagents contained within a compartment including a hydrogen peroxide containing composition and a matrix, will be forced to exit the compartment through a mixing baffle in response to the externally applied pressure.

15 A further embodiment of the invention includes a method for bleaching teeth including preparing a composition as described above and administering the composition to the tooth surface.

16 DETAILED DESCRIPTION OF THE INVENTION

17 The present invention comprises compositions and methods for bleaching tooth enamel in situ which allow the use of reduced concentrations of hydrogen peroxide in tooth-bleaching compositions in order to achieve effective tooth bleaching in a contact time of less than one hour.

18 The tooth surface is defined here and in the claims as a portion of a tooth which is directly responsible for the stained appearance of said tooth. The term tooth surface generally means a tooth's acquired pellicle, plaque, enamel, and combinations thereof.

19 The matrix is defined here and in the claims as the gel, paste, or liquid in which the hydrogen peroxide containing compound is placed for administration to the subject.

20 The subject referred to here and in the claims is commonly a human subject but also includes domestic animals.

21 An important aspect of the present invention is the finding that the efficiency of the bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5, more particularly a pH in the range of 6-10, for example in a range of pH of 7-10, more particularly between 8.0 and 9.5, providing that the pH is maintained at a substantially constant range throughout the tooth-bleaching process and a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)

22 Suitable pH adjusting agents include, but are not limited to, sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, TRIS and triethanolamine.

23 Examples of calcium chelating agents include any of the calcium chelating agents known in the art. Examples include EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates. The use of citric acid, sodium acid pyrophosphate and disodium EDTA are shown in Table 1 and Table 2. The biological efficacy of sodium acid pyrophosphate is shown in Table 4. Without being bound to any particular theory, it is proposed that calcium precipitation in the form of calcium phosphates arise in the intercrystalline interstices of the tooth at elevated pHs and this gives rise to a blockage of movement of the peroxide into the tooth with a resulting negative effect on tooth bleaching. Calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth-bleaching effect.

24 The composition may also contain a stabilizing agent for removing from solution, metal ions that interfere with the action of the hydrogen peroxide.

In certain formulations, a single component may act either as a calcium chelating agent or as a stabilizing agent or may serve both functions.

25 The ability to maintain a constant pH range above 5.5 throughout the period of tooth bleaching coupled with the inhibition of calcium precipitation that normally occurs at pH levels above 5.5, has resulted in a formulation that is suitable for use in the home and is capable of achieving detectable tooth bleaching in less than 30 minutes. Furthermore, multiple treatments (each treatment lasting no longer than 30 minutes) have been demonstrated to substantially whiten teeth (Example 5). In Example 5, 14 treatments using the inventive formulation, were administered for twenty minutes, twice a day over seven days. A mean .DELTA.E of 7.32 was observed denoting a substantial tooth-bleaching effect compared with a .DELTA.E of 4.73 using a prior art formulation for a period of time that was three times longer than that of the novel formulation.

26 According to the invention, additional agents having tooth-bleaching effect may be used to achieve detectable tooth bleaching in less than 30 minutes. For example, sodium percarbonate has been demonstrated to be very effective at tooth bleaching when maintained at a pH that is greater than 5.5, more preferably in the range of 7-10, more particularly 8-9.5 that includes a calcium chelating agent. This composition differs from carbamide peroxide in that there is no acidification of that solution that results upon its dissociation. Consequently, the reagent may be maintained at a constant elevated pH for an extended period of time without the necessity for adding buffering reagents beyond that naturally supplied in the saliva. Unlike carbamide peroxide, however, the percarbonate is prepared in a formulation that does not include glycerine and is only slowly permeated by water whereupon hydrogen peroxide is released. For this reason, it may be desirable, but is not essential, to prepare the percarbonate in a two-component composition, the two components being mixed before use so as to accelerate the tooth-bleaching effect (Examples 1 and 2). Formulations containing two components may be applied to the dental tray by squeezing a tube in much the same way as a single component. The mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer such that on squeezing the tube, material from each of the compartments is forced through the static mixer and are mixed together before emerging from a single exit in the tube.

DETAILED DESCRIPTION:

1 The present invention has important health benefits that follow from shorter contact times of the tooth with hydrogen peroxide as well as the need for lower concentrations of peroxide to achieve a desired tooth-bleaching effect.

2 EXAMPLE 1

3 Composition of a Stable Tooth-Bleaching Formulation Suitable for use in a One Component System.

4 The formulations below utilized ultrapure components to avoid destabilization caused by metal ion contaminants. The chelating agent used here is one of disodium EDTA (1C), citric acid (1B), and sodium acid pyrophosphate (1F). The pH is modified using one of sodium hydroxide monohydrate (1A, 1B, 1C), ammonium hydroxide (1F,1G), Tris(hydroxymethyl) aminomethane (1D), and triethanolamine (1E). Carbopol is a high molecular weight crosslinked polyacrylic acid thickening agent. Hydrogen peroxide is used as the oxidizing agent.

TABLE 1

Example 1	A	B	C	D	E	F	G
Ingredient				WEIGHT PERCENT			
Distilled Water	86.41	86.21	86.31	72.80	79.52	86.50	73.81
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02	0.02	0.02	0.03	0.02	0.30	0.40
Sodium stannate trihydrate	0.02	0.02	0.02	0.03	0.02	0.05	0.05
Citric acid	--	0.20	--	--	--	--	0.10
Calcium disodium EDTA	--	--	0.10	--	--	--	--
Sodium acid pyrophosphate	--	--	--	--	--	0.30	--
Hydrogen Peroxide 35%	10.30	10.30	10.30	17.14	17.14	8.60	17.14
Carbopol 974P (BF Goodrich)	2.50	2.50	2.50	5.00	--	3.00	5.00
Carbopol 934P (BF Goodrich)	--	--	--	--	2.00	--	--
Sodium Hydroxide Monohydrate	to pH 7.0	to pH 7.0	to pH 7.0	--	--	--	--
Ammonium hydroxide 28%	--	--	--	--	--	to pH 6.5	to pH 8.5
Tris(hydroxymethyl) aminomethane	--	--	--	to pH 8.0	--	--	--
Triethanolamine	--	--	--	--	to pH 6.0	--	--
Total	100	100	100	100	100		

100 100

pH @ 25 deg. C. 7.0 7.0 7.0 8.0 6.0

6.5 8.5

5 The above formulations were prepared by dissolving the stabilizers 1-hydroxyethylidene-1,1-diphosphonic acid and the sodium stannate trihydrate in the distilled water using a Kynar-coated propeller-type agitator (reserving enough water, if necessary, to dissolve the neutralizer in the final step). The hydrogen peroxide was then added slowly to this mixture. The Carbopol 974P was then added to the distilled water/stabilizer/hydrogen peroxide mixture slowly while a vortex was formed with the agitator blade. This dispersion was then placed in a Kynar-coated vacuum double planetary mixer to which the pH adjusting agent was added slowly to affect neutralization of the Carbopol 974P and to adjust the final composition pH. The resulting composition was a transparent, viscous gel and was packaged in foil/plastic laminate tubes having a polyethylene product contact liner.

6 EXAMPLE 2

7 A Two Component Alkaline Tooth-Bleaching Formulation.

8 A hydrogen peroxide-releasing composition was formulated which utilized sodium percarbonate in an anhydrous gel, and was designed to be combined with a separate aqueous gel prior to use in order to dissolve the sodium percarbonate to form hydrogen peroxide and sodium carbonate. The pH of this composition, shown in Table 2, when combined in a volume ratio of 1 to 1, was 9.0. The chelating agents used here are EDTA and sodium acid pyrophosphate.

TABLE 2

EXAMPLE 2	PART A	PART B
INGREDIENT	WEIGHT PERCENT	
Distilled Water	--	95.20
Polyethylene glycol 400	83.00	--
Sodium percarbonate (powder)	12.00	--
EDTA	--	0.20
Sodium acid pyrophosphate	--	0.30
Carbopol 974P (B F Goodrich)	2.50	4.00
Sodium Hydroxide Monohydrate	--	to pH 7.0
Tris(hydroxymethyl)aminomethane	2.50	--
Total	100	100

9 The above composition parts were prepared as follows:

10 Part A--The Carbopol was dispersed in the polyethylene glycol using a

propeller-type agitator with Kynar-coated product contact surfaces. The resulting dispersion was added to a Kynar-coated vacuum double planetary mixer (as in Example 1) and neutralized with the tris(hydroxymethyl)aminomethane under low shear mixing. To the resultant neutralized Carbopol gel, sodium percarbonate was added and dispersed until the composition was a homogenous white paste.

11 Part B--The Carbopol was added to the water (in which the EDTA and sodium acid pyrophosphate had already been dissolved) and agitated as above. The resulting dispersion was transferred to the Kynar-coated vacuum double planetary mixer and neutralized with the sodium hydroxide monohydrate under low shear mixing. The final gel was clear and viscous, with a pH of around 7.0.

12 Example 3

13 Preparation of a Tooth-Bleaching Formulation having Acidic pH

14 In order to demonstrate the superior ability of the inventive hydrogen peroxide gel composition of Examples 1 and 2 to bleach teeth, a composition was prepared which was similar to that of Example 1E, except that the pH was adjusted to 4.5.

TABLE 3

INGREDIENT	PERCENT
Distilled water	79.82
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02
Sodium stannate trihydrate	0.02
Carbopol 974P	2.00
Hydrogen Peroxide 35%	17.14
Triethanolamine	1.00
TOTAL	100.00

15 The formulation was prepared as in Example 1, resulting in a transparent, viscous gel with a pH of approximately 4.5. The formulation is similar to 1E, the difference lying in the pH of the composition.

16 Example 4

17 Assay to Determine Tooth Bleaching.

18 Bovine incisors, which had been imbedded in an acrylic matrix such that the buccal surfaces presented themselves on the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, FeCl.sub.3, and Sarcina lutea, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes,

whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as .DELTA.E. Absolute color change is defined as the square root of the sum of the squares of all color components (L,a, and b).

[(.DELTA.L).sup.2 +(.DELTA.a).sup.2 +(.DELTA.b).sup.2]=.DELTA.E

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	.DELTA.E
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

19 This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased .DELTA.E from 4.29 to 6.27.

20 The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in .DELTA.E in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

21 Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

22 Example 5

23 In Vivo Demonstration of Tooth Bleaching

24 Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

25 One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

26 The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

27 The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	Initial Color a	Initial Color b	Final Color L	Final Color a	Final Color b	.DELTA.E
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

28 The average .DELTA.E for the Example IB group was 7.32, whereas the average .DELTA.E for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a

shorter exposure time than a prior art composition.

CLAIMS:

I claim:

1. A single exit dual compartment squeeze tube with a static mixer, whose compartments are adapted to keep apart two formulations and whose two compartments respectively include:

a first formulation comprising a hydrogen peroxide precursor compound selected from the group consisting of an alkali metal percarbonate, carbamide peroxide, calcium peroxide, and an alkali metal perborate, a thickener, a carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and is substantially free of water; and

a second formulation comprising an alkaline pH-adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially tree of the hydrogen peroxide precursor compound; whereby squeezing the tube forces material from each compartment through the static mixer to form a thickened, aqueous, substantially bicarbonate free, and substantially abrasive free hydrogen peroxide containing mixture before emerging from the single exit in the tube, wherein the mixture has a range of pH between approximately 6 and approximately 10.

2. The single exit dual compartment squeeze tube according to claim 1, wherein the hydrogen peroxide precursor compound is a percarbonate salt.

3. The single exit dual compartment squeeze tube according to claim 2, wherein the percarbonate salt is selected from the group consisting of sodium and potassium percarbonate.

4. The single exit dual compartment squeeze tube according to claim 1, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates.

5. The single exit dual compartment squeeze tube according to claim 4, wherein the calcium chelating agent further acts as a stabilizing agent for the hydrogen peroxide precursor compound.

6. The single exit dual compartment squeeze tube according to claim 8, wherein the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

7. The single exit dual compartment squeeze tube according to claim 1, wherein the composition is capable of a detectable tooth-bleaching effect within 30 minutes.

8. The single exit dual compartment squeeze tube according to claim 1, the first formulation comprising:

less than about 0.5% by weight, based on the weight of the mixture, of the calcium chelating agent.

9. The single exit dual compartment squeeze tube according to claims 8, wherein the first formulation has less than about 0.1% by weight, based on the weight of the composition, of the calcium chelating agent.

10. The single exit dual compartment squeeze tube according to claim 1, wherein the second formulation is aqueous.

11. The single exit dual compartment squeeze tube according to claim 1, wherein

the thickening agent is a high molecular weight cross linked polyacrylic acid.

12. A single exit dual compartment squeeze tube with a static mixer, whose compartments are adapted to keep apart two formulations and whose two compartments respectively include:

a first formulation comprising hydrogen peroxide, a thickener, an aqueous carrier and a chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of the hydrogen peroxide; whereby squeezing the tube forces material from each compartment through the static mixer to form a thickened, aqueous, substantially bicarbonate free, and substantially abrasive free hydrogen peroxide containing mixture before emerging from the single exit in the tube, wherein the mixture has a range of pH between approximately 6 and approximately 10.

13. The single exit dual compartment squeeze tube according to claim 12, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the mixture.

14. The single exit dual compartment squeeze tube according to claim 12, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates.

15. The single exit dual compartment squeeze tube according to claim 12, wherein the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

16. The single exit dual compartment squeeze tube according to claim 1, wherein the mixture is capable of a detectable tooth-bleaching effect within 30 minutes.

17. The single exit dual compartment squeeze tube according to claim 12, the first formulation comprising:

less than about 0.5% by weight, based on the weight of the mixture, of the calcium chelating agent.

18. The single exit dual compartment squeeze tube according to claim 12, wherein the first formulation has less than about 0.1% by weight, based on the weight of the composition, of the calcium chelating agent.

19. The single exit dual compartment squeeze tube according to claim 12, wherein the concentration of hydrogen peroxide in the mixture is in a range between approximately 5% and approximately 12% by weight of the mixture.

20. The single exit dual compartment squeeze tube according to claim 12, wherein the thickening agent is a high molecular weight cross linked polyacrylic acid.

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L1: Entry 54 of 852 File: USPT Nov 6, 2001

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TITLE: Tooth bleaching compositions

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Montgomery; Robert Eric	Monterey	MA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
R. Eric Montgomery	Monterey	MA			02
Idex Dental Sciences, Inc.	Monterey	MA			02

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PRIOR-ART-DISCLOSED:

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ART-UNIT: 164

PRIMARY-EXAMINER: Rose; Shep K.

ABSTRACT:

The present invention relates to improved dental compositions and methods for bleaching teeth. More specifically, this invention is directed towards hydrogen peroxide-containing compounds that are maintained at a substantially constant pH range of 6.0-10.0 during the tooth-bleaching procedure in the presence of a calcium chelating agent.

10 Claims, 0 Drawing figures
Exemplary Claim Number: 1

BRIEF SUMMARY:

1 TECHNICAL FIELD

2 The present invention relates to improved dental bleaching compositions and methods for bleaching teeth.

3 BACKGROUND ART

4 White teeth have long been considered cosmetically desirable. Unfortunately, teeth become almost invariably discolored in the absence of intervention. The tooth structures which are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Tooth enamel is predominantly formed from inorganic material, mostly in the form of hydroxyapatite crystals and further contains approximately 5% organic material primarily in the form of collagen. In contrast, dentin is composed of about 20% protein including collagen, the balance consisting of inorganic material, predominantly hydroxyapatite crystals, similar to that found in enamel. The acquired pellicle is a proteinaceous layer on the surface of tooth enamel which reforms rapidly after an intensive tooth cleaning.

5 Staining of teeth results from extrinsic and/or intrinsic staining. Extrinsic staining of the acquired pellicle arises as a result of compounds such as tannins and polyphenolic compounds which become trapped in and tightly bound to the proteinaceous layer on the surface of the teeth. This type of staining can usually be removed by mechanical methods of tooth cleaning. In contrast, intrinsic staining occurs when staining compounds penetrate the enamel and even

the dentin or arise from sources within the tooth. This type of staining is not amenable to mechanical methods of tooth cleaning and chemical methods are required.

6 Consequently, tooth-bleaching compositions generally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle; and (2) gels, pastes, or liquids that accomplish the tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is removed. In some cases, the mechanical process is supplemented by an auxiliary chemical process which may be oxidative or enzymatic.

7 The majority of professionally-monitored at-home tooth-bleaching compositions act by oxidation. These compositions are dispensed directly to a patient for use in a custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to 12 hours. The slow rate of bleaching is in large part, the consequence of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerine and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubes toward nerve endings in the tooth. This movement is enhanced by the carriers for the carbamide peroxide. In fact, it has been determined that glycerine, propylene glycol and polyethylene glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

8 Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization; penetration of the intact enamel and dentin by the bleaching agents, so as to reach the pulp chamber of a vital tooth thereby risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva with resulting leaching from the dental tray and subsequent digestion.

9 The stability of existing formulations of hydrogen peroxide-containing tooth-bleaching compositions in terms of shelf-life as well as over the period of use in the mouth, depends, in general, on an acidic pH. The hydrogen peroxide becomes markedly less stable as the pH increases. Indeed, Frysh, et al. (Journal of Esthetic Dentistry Vol. 7, No. 3, pp. 130-133,1995) described the use of high concentration (35%) of hydrogen peroxide solutions at an initial alkaline pH, which was required to be formulated immediately before use and was administered in the form of a liquid to extracted teeth to achieve tooth bleaching. Phillips and Bowles (IADR Abstract J. Dent.res 75,1996) have demonstrated that hydrogen peroxide penetrates the enamel of extracted teeth less readily over a 15 minute period at pH 9.0 than at pH 4.5. Carbamide peroxide compositions have been formulated at a pH of 5.0-6.5 using hygroscopic carriers and maintaining a low water content. This type of formulation is problematic with regard to enhanced tooth sensitivity. On contact with saliva, the water content of the formulation increases, causing the carbamide to disassociate into urea and hydrogen peroxide and the pH to be decreased. In fact, the equilibrium pH of a 10% carbamide peroxide solution is approximately 3.45 and a typical commercially-available tooth-bleaching gel with 10% carbamide peroxide when combined with saliva in a 1:1 weight ratio has an initial pH of 5.6 and gradually decreases to pH 4.8 after 8 hours.

10 Thus, currently available tooth-bleaching compositions that rely on hydrogen peroxide as oxidizing agents, all release hydrogen peroxide from precursors at low pH levels despite the low rates of tooth-bleaching activity.

11 There is a need for a home use tooth-bleaching product that is stable, easy to use, and rapid-acting that utilizes reduced amounts of hydrogen peroxide and is capable of administration to a patient by means of a dental tray. There is a further need for a tooth-bleaching composition that may reduce hard and soft tissue irritation, tooth sensitivity, and bleaching composition ingestion to further increase patient compliance.

12 SUMMARY OF THE INVENTION

13 The invention satisfies the above needs. An embodiment of the invention includes a tooth-bleaching composition for contacting a tooth surface in a subject that includes a hydrogen peroxide-containing compound. Furthermore the composition includes a matrix for administering the hydrogen peroxide-containing compound to the tooth surface. The matrix comprises a thickening agent, an agent for stabilizing the hydrogen peroxide-containing compound, a pH adjusting agent and a calcium chelating agent, wherein the pH of the tooth-bleaching composition during the bleaching process is substantially constant within a range of pH 6.0-10.

14 A further embodiment of the invention includes a dosage delivery unit for tooth bleaching, including a multi-chamber vessel wherein each chamber is responsive to an applied pressure from an external source, such that a mixture of reagents contained within a compartment including a hydrogen peroxide containing composition and a matrix, will be forced to exit the compartment through a mixing baffle in response to the externally applied pressure.

15 A further embodiment of the invention includes a method for bleaching teeth including preparing a composition as described above and administering the composition to the tooth surface.

16 DETAILED DESCRIPTION OF THE INVENTION

17 The present invention comprises compositions and methods for bleaching tooth enamel in situ which allow the use of reduced concentrations of hydrogen peroxide in tooth-bleaching compositions in order to achieve effective tooth bleaching in a contact time of less than one hour.

18 The tooth surface is defined here and in the claims as a portion of a tooth which is directly responsible for the stained appearance of said tooth. The term tooth surface generally means a tooth's acquired pellicle, plaque, enamel, and combinations thereof.

19 The matrix is defined here and in the claims as the gel, paste, or liquid in which the hydrogen peroxide containing compound is placed for administration to the subject.

20 The subject referred to here and in the claims is commonly a human subject but also includes domestic animals.

21 An important aspect of the present invention is the finding that the efficiency of the bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5, more particularly a pH in the range of 6-10, for example in a range of pH of 7-10, more particularly between 8.0 and 9.5, providing that the pH is maintained at a substantially constant range throughout the tooth-bleaching process and a calcium chelating agent is included in the composition to prevent precipitation of calcium ions. (Table 1-4)

22 Suitable pH adjusting agents include, but are not limited to, sodium hydroxide,

potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, TRIS and triethanolamine.

23 Examples of calcium chelating agents include any of the calcium chelating agents known in the art. Examples include EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates. The use of citric acid, sodium acid pyrophosphate and disodium EDTA are shown in Table 1 and Table 2. The biological efficacy of sodium acid pyrophosphate is shown in Table 4. Without being bound to any particular theory, it is proposed that calcium precipitation in the form of calcium phosphates arise in the intercrystalline interstices of the tooth at elevated pHs and this gives rise to a blockage of movement of the peroxide into the tooth with a resulting negative effect on tooth bleaching. Calcium chelating agents may prevent this precipitation of calcium ions with the associated observed improvement of tooth-bleaching effect.

24 The composition may also contain a stabilizing agent for removing from solution, metal ions that interfere with the action of the hydrogen peroxide. In certain formulations, a single component may act either as a calcium chelating agent or as a stabilizing agent or may serve both functions.

25 The ability to maintain a constant pH range above 5.5 throughout the period of tooth bleaching coupled with the inhibition of calcium precipitation that normally occurs at pH levels above 5.5, has resulted in a formulation that is suitable for use in the home and is capable of achieving detectable tooth bleaching in less than 30 minutes. Furthermore, multiple treatments (each treatment lasting no longer than 30 minutes) have been demonstrated to substantially whiten teeth (Example 5). In Example 5, 14 treatments using the inventive formulation, were administered for twenty minutes, twice a day over seven days. A mean .DELTA.E of 7.32 was observed denoting a substantial tooth-bleaching effect compared with a .DELTA.E of 4.73 using a prior art formulation for a period of time that was three times longer than that of the novel formulation.

26 According to the invention, additional agents having tooth-bleaching effect may be used to achieve detectable tooth bleaching in less than 30 minutes. For example, sodium percarbonate has been demonstrated to be very effective at tooth bleaching when maintained at a pH that is greater than 5.5, more preferably in the range of 7-10, more particularly 8-9.5 that includes a calcium chelating agent. This composition differs from carbamide peroxide in that there is no acidification of that solution that results upon its dissociation. Consequently, the reagent may be maintained at a constant elevated pH for an extended period of time without the necessity for adding buffering reagents beyond that naturally supplied in the saliva. Unlike carbamide peroxide, however, the percarbonate is prepared in a formulation that does not include glycerine and is only slowly permeated by water whereupon hydrogen peroxide is released. For this reason, it may be desirable, but is not essential, to prepare the percarbonate in a two-component composition, the two components being mixed before use so as to accelerate the tooth-bleaching effect (Examples 1 and 2). Formulations containing two components may be applied to the dental tray by squeezing a tube in much the same way as a single component. The mixing of the two components can be readily achieved using a multi-component tube containing a baffle, otherwise known in the art as a static mixer such that on squeezing the tube, material from each of the compartments is forced through the static mixer and are mixed together before emerging from a single exit in the tube.

27 The present invention has important health benefits that follow from shorter contact times of the tooth with hydrogen peroxide as well as the need for lower concentrations of peroxide to achieve a desired tooth-bleaching effect.

DETAILED DESCRIPTION:

1 . EXAMPLE 1

2 Composition of a Stable Tooth-bleaching Formulation Suitable for Use in a One Component System

3 The formulations below utilized ultrapure components to avoid destabilization caused by metal ion contaminants. The chelating agent used here is one of disodium EDTA (1C), citric acid (1B), and sodium acid pyrophosphate (1F). The pH is modified using one of sodium hydroxide monohydrate (1A, 1B, 1C), ammonium hydroxide (1F,1G), Tris(hydroxymethyl) aminomethane (1D), and triethanolamine (1E). Carbopol is a high molecular weight crosslinked polyacrylic acid thickening agent. Hydrogen peroxide is used as the oxidizing agent.

TABLE 1

Example 1	A	B	C	D	E	F	G
Ingredient	WEIGHT PERCENT						
Distilled Water	86.41	86.21	86.31	72.80	79.52	86.50	73.81
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02	0.02	0.02	0.03	0.02	0.30	0.40
Sodium stannate trihydrate	0.02	0.02	0.02	0.03	0.02	0.05	0.05
Citric acid	--	0.20	--	--	--	--	0.10
Calcium disodium EDTA	--	--	0.10	--	--	--	--
Sodium acid pyrophosphate	--	--	--	--	--	0.30	--
Hydrogen Peroxide 35%	10.30	10.30	10.30	17.14	17.14	8.60	17.14
Carbopol 974P (BF Goodrich)	2.5	2.5	2.5	5.00	--	3.00	5.00
Carbopol 934P (BF Goodrich	--	--	--	--	2.00	--	--
Sodium Hydroxide	to pH 7.0	to pH 7.0	to pH 7.0	--	--	--	--

Monohydrate							
Ammomium hydroxide 28%	--	--	--	--	--	to pH 6.5	to pH 8.5
Tris(hydroxymethyl) aminomethane	--	--	--	to pH 8.0	--	--	--
Triethanolamine	--	--	--	--	to pH 6.0	--	--
Total	100	100	100	100	100	100	100
pH @ 25 deg. C.	7.0	7.0	7.0	8.0	6.0	6.5	8.5

4 The above formulations were prepared by dissolving the stabilizers 1-hydroxyethylidene-1,1-diphosphonic acid and the sodium stannate trihydrate in the distilled water using a Kynar-coated propeller-type agitator (reserving enough water, if necessary, to dissolve the neutralizer in the final step). The hydrogen peroxide was then added slowly to this mixture. The Carbopol 974P was then added to the distilled water/stabilizer/hydrogen peroxide mixture slowly while a vortex was formed with the agitator blade. This dispersion was then placed in a Kynar-coated vacuum double planetary mixer to which the pH adjusting agent was added slowly to affect neutralization of the Carbopol 974P and to adjust the final composition pH. The resulting composition was a transparent, viscous gel and was packaged in foil/plastic laminate tubes having a polyethylene product contact liner.

5 EXAMPLE 2

6 A Two Component Alkaline Tooth-bleaching Formulation

7 A hydrogen peroxide-releasing composition was formulated which utilized sodium percarbonate in an anhydrous gel, and was designed to be combined with a separate aqueous gel prior to use in order to dissolve the sodium percarbonate to form hydrogen peroxide and sodium carbonate. The pH of this composition, shown in Table 2, when combined in a volume ratio of 1 to 1, was 9.0. The chelating agents used here are EDTA and sodium acid pyrophosphate.

TABLE 2

EXAMPLE 2	PART A	PART B
INGREDIENT	WEIGHT PERCENT	
Distilled Water	--	95.20
Polyethylene glycol 400	83.00	--
Sodium percarbonate (powder)	12.00	--

EDTA	--	0.20
Sodium acid pyrophosphate	--	0.30
Carbopol 974P (B F Goodrich)	2.50	4.00
Sodium Hydroxide Monohydrate	--	to pH 7.0
Tris(hydroxymethyl)aminomethane	2.50	--
Total	100	100

8 The above composition parts were prepared as follows:

9 Part A--The Carbopol was dispersed in the polyethylene glycol using a propeller-type agitator with Kynar-coated product contact surfaces. The resulting dispersion was added to a Kynar-coated vacuum double planetary mixer (as in Example 1) and neutralized with the tris(hydroxymethyl)aminomethane under low shear mixing. To the resultant neutralized Carbopol gel, sodium percarbonate was added and dispersed until the composition was a homogenous white paste.

10 Part B--The Carbopol was added to the water (in which the EDTA and sodium acid pyrophosphate had already been dissolved) and agitated as above. The resulting dispersion was transferred to the Kynar-coated vacuum double planetary mixer and neutralized with the sodium hydroxide monohydrate under low shear mixing. The final gel was clear and viscous, with a pH of around 7.0.

11 EXAMPLE 3

12 Preparation of a Tooth-bleaching Formulation Having Acidic pH

13 In order to demonstrate the superior ability of the inventive hydrogen peroxide gel composition of Examples 1 and 2 to bleach teeth, a composition was prepared which was similar to that of Example 1E, except that the pH was adjusted to 4.5.

TABLE 3

INGREDIENT	PERCENT
Distilled water	79.82
1-Hydroxyethylidene-1,1-diphosphonic acid	0.02
Sodium stannate trihydrate	0.02
Carbopol 974P	2.00
Hydrogen Peroxide 35%	17.14
Triethanolamine	1.00
TOTAL	100.00

14 The formulation was prepared as in Example 1, resulting in a transparent, viscous gel with a pH of approximately 4.5. The formulation is similar to 1E,

the difference lying in the pH of the composition.

15 EXAMPLE 4

16 Assay to Determine Tooth Bleaching

17 Bovine incisors, which had been imbedded in an acrylic matrix such that the buccal surfaces presented themselves on the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, $FeCl_3$, and Sarcina lutea, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$[(\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2] = \Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	Initial Color a	Initial Color b	Final Color L	Final Color a	Final Color b	.DELTA.E
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

18 This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased .DELTA.E from 4.29 to 6.27.

19 The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in .DELTA.E in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

20 Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

21 EXAMPLE 5

22 In vivo Demonstration of Tooth Bleaching

23 Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

24 One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

25 The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

26 The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

	Product/	Treatment	Initial Color			Final Color			
Patient #	Example	Time (minutes)	L	a	b	L	a	b	.DELTA.E
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65

4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	
2.10	6.04							
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	
2.44	4.09							
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	
4.75	4.07							

27 The average .DELTA.E for the Example 1B group was 7.32, whereas the average .DELTA.E for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

CLAIMS:

I claim:

1. A method for bleaching the teeth of a subject comprising:

providing a multi-chamber vessel, the vessel including a first chamber having a first formulation including a hydrogen peroxide precursor compound selected from the group consisting of an alkali metal percarbonate, carbamide peroxide, calcium peroxide, and an alkali metal perborate, a thickener, a carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and is substantially free of water and

a second chamber having a second formulation including an alkaline pH adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of the hydrogen peroxide precursor compound;

applying pressure to the multi-chamber vessel, so as to force the first and second formulations through a mixing baffle to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous, hydrogen peroxide containing composition and being bicarbonate free and abrasive free and having a pH of between approximately 6 and approximately 10; and

contacting the mixture to the teeth of the subject for less than one hour.

2. A method according, to claim 1, wherein the pH adjusting agent is ammonium hydroxide and the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

3. A method according to claim 1, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates, alkali metal polyphosphates, diphosphonic acids, and combinations thereof.

4. A method according to claim 1, wherein the mixture has a water content of more than about 70% by weight of the mixture.

5. A method according to claim 1 further comprising:

maintaining the mixture upon the teeth for an extended time period, the time period being between approximately 10 minutes and approximately 30 minutes.

6. A method for bleaching the teeth of a subject comprising:

providing a multi-chamber vessel, the vessel including a first chamber having a first formulation including hydrogen peroxide, a thickener, an aqueous carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and

a second chamber having a second formulation including an alkaline pH adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of hydrogen peroxide;

applying pressure to the multi-chamber vessel, so as to force the first and second formulations through a mixing baffle to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous, hydrogen peroxide containing composition and being bicarbonate free and abrasive free and having a pH of between approximately 6 and approximately 10; and

contacting the mixture to the teeth of the subject for less than one hour.

7. A method according to claim 6 wherein the pH adjusting agent is ammonium hydroxide and the calcium chelating agent is 1-hydroxyethylidene-1,1 -diphosphonic acid.

8. A method according to claim 6, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates, alkali metal polyphosphates, diphosphonic acids, and combinations thereof.

9. A method according to claim 1, wherein the mixture has a water content of more than about 70% by weight of the mixture.

10. A method according to claim 1 further comprising:

maintaining the mixture upon the teeth for an extended time period, the time period being between approximately 10 minutes and approximately 30 minutes.

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US-PAT-NO: 6065645
DOCUMENT-IDENTIFIER: US 6065645 A

TITLE: Double-barreled syringe with detachable locking mixing tip

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Sawhney; Ravi K.	Calabasas	CA		
Hussey; Lance	Sherman Oaks	CA		
Hayman; Robert G.	Pacific Palisades	CA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Discus Dental Impressions, Inc.	Culver City	CA			02

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PARENT-CASE:
RELATED APPLICATIONS This patent application is a continuation-in-part (CIP) patent application of U.S. patent application Ser. No. 08/829,944, filed on Apr. 1, 1997 now U.S. Pat. No. 5,819,988 and entitled DOUBLE-BARRELED SYRINGE WITH DETACHABLE LOCKING MIXING TIP, the entire contents of which are hereby expressly incorporated by reference.

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FIELD-OF-SEARCH: 222/137, 222/145.6, 222/153.09, 222/386, 222/459, 239/399

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

Search Selected Search ALL

	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
☐	3166221	January 1965	Nielsen	222/137
☐	3330444	July 1967	Raypholtz	222/137
☐	4538920	September 1985	Drake	366/177
☐	4974756	December 1990	Pearson et al.	222/137
☐	5413253	May 1995	Simmen	222/137
☐	5609271	March 1997	Keller et al.	222/145.6
☐	5819988	October 1998	Sawhney et al.	222/137

ART-UNIT: 374

PRIMARY-EXAMINER: Kaufman; Joseph A.

ABSTRACT:

A double-barreled syringe is provided which includes a mixing tip which is detachable after the tip is locked to the syringe body, so that the tip may be replaced by a locking cap. Locking occurs when a neck extending from the body between two shoulders is inserted into a bore in the tip (or, alternatively, the cap) and the tip is rotated so that two symmetrically opposed tabs attached to the tip are each received within a recess determined by a shoulder and a locking rib attached to the shoulder, and two diametrically opposed detents extending from the neck are each received within a recess in the bore surface.

65 Claims, 23 Drawing figures
Exemplary Claim Number: 1
Number of Drawing Sheets: 7

BRIEF SUMMARY:

1 BACKGROUND OF INVENTION

2 1. Field of the Invention

3 The present invention relates to multiple-barreled devices for mixing together and dispensing viscous substances. More particularly, the invention relates to a double-barreled syringe having a double-barreled plunger of unitary construction for dispensing an admixture formed when two gels stored in the barrels are simultaneously discharged into a mixing tip having a five section static mixing element. The tip, which interlocks with the syringe body, is detachable and may be replaced by a locking closure cap to prevent leakage when the syringe is not in use. The locking closure cap preferably has a liner which mitigates undesirable leakage during transport and storage.

4 2. Description of the Related Art

5 Devices for mixing and dispensing a viscous fluid having separately stored constituents wherein a mixing portion is detachably connected to a storage portion are known in the art. U.S. Pat. No. 5,413,253 to C. Simmen discloses a static mixer for connection to a cartridge having at least two chambers containing different materials. The mixer is connected to the cartridge by inserting hollow circular make prongs and arcuate positioning keys of a center plug within corresponding female outlets in the cartridge. The plug is rotatably mounted within the collar of a sleeve. The mixer is locked to the cartridge by rotating the collar until opposed tabs on the sleeve engage with locking arms on the dispensing end of the cartridge.

6 U.S. Pat. No. 4,538,920 to G. E. Drake discloses a double-barreled syringe for mixing and dispensing a two-component material such as a resin and its hardener. Both a mixing tip and a static mixing element located within the tip bore are flexibly rotationally aligned with the syringe body so that the first blade of the mixing element is generally perpendicular to the plane of contiguity between the two component streams exiting a syringe body outlet. The mixing tip is connected to the body by centering the tip inlet over the body outlet while aligning the tip so that it can be pushed between opposed bayonet locking tabs, each having a prong and a stop surface, and then rotating the tip so that opposed ramps on the tip inlet end are wedged between the prongs, and a stop surface proximate to each ramp engages a tab stop surface.

7 Although either of these devices enables the storage and mixing portions to be connected and then detached multiple times, both are so complex as to be unsuitable for mass production of inexpensive, throwaway dispensers. What is needed is a device which on demand can thoroughly mix two-component viscous materials and dispense a desired amount of the admixture, which will not leak when set aside, and which can be mass produced at relatively little cost.

8 OBJECTS OF THE INVENTION

9 Accordingly, it is an object of the present invention to provide a simple, reliable and convenient device which simultaneously dispenses equal amounts of two well mixed viscous materials as an admixture.

10 Another object of the invention is to provide a device which can be repetitively used to dispense desired amounts of an admixture.

11 A further object of the invention is to provide a device having a storage portion and a mixing-dispensing portion which repetitively can be easily connected and then detached, wherein the storage portion does not leak during storage and transport thereof.

12 A still further object of the invention is to provide a device that is inexpensive to manufacture.

13 Other objects of the invention will become evident when the following description is considered with the accompanying drawing figures. In the figures and description, numerals indicate the various features of the invention, like numerals referring to like features throughout both the drawings and the descriptions.

14 SUMMARY OF INVENTION

15 These and other objects are achieved by the present invention which provides a double-barreled syringe wherein one barrel contains a hydrogen peroxide water-based gel formulation used for teeth whitening, and the other contains a gel formulation including compounds that will accelerate the release of oxygen from the first formulation and consequently increase the reaction rate of the teeth whitening process. The syringe dispenses an admixture formed when the two formulations are simultaneously discharged into a mixing tip having a static mixing element. The tip, which is in locking connection with the syringe body, is replaced by a locking closure cap to prevent leakage when the syringe is not in use.

16 The syringe body includes a double-barrel assembly having juxtaposed first and second barrels having a common length and a generally cylindrical bore of a common diameter. Each barrel is bounded at a discharge end by first and second shoulders, respectively, with each shoulder having a generally planar surface. The surfaces are coplanar and contiguous. A generally cylindrical neck extends from and is symmetrically disposed between the shoulders. The neck includes first and second outlet passages. Each barrel at its opposite (plunger) end closely receives a piston within its bore. An arcuately-shaped finger-grip

circumscribes the contiguous plunger ends of the barrels.

17 The syringe body further includes a double-plunger assembly having juxtaposed first and second plungers of a common length. Each plunger extends at a proximal end in an end-piece rigidly attached to one of the pistons, and is rigidly attached at a distal end to a thumb-rest common to the plungers.

18 Alternatively, each plunger has a seal formed integrally therewith at a

19 distal end thereof. The seal preferably comprises a flare having a wall thickness which is sufficiently thin as to flexibly conform to the bore within which it is contained and thus seal the plunger upon which it is formed with respect to the bore.

20 Further, according to the preferred embodiment of the present invention an alignment ring is formed proximate the distal end of each plunger. The alignment ring is formed proximal of the seal. The alignment ring enhances alignment of the seal with respect to the barrel within which the seal is disposed. The alignment ring is coupled comparatively flexibly to the shaft of the plunger and the alignment ring is coupled comparatively rigidly to the seal, so as to allow the combination of the alignment ring and the seal to move together as a unit with respect to the shaft while also causing the alignment ring and the seal to remain comparatively fixed in position with respect to one another. In this manner, the alignment ring and the seal remain aligned with respect to the bore within which they are disposed regardless of bending of the shaft of the plunger which may occur during use.

21 According to the preferred embodiment of the present invention, the alignment ring is attached to the shaft by a first neck and the seal is attached to the alignment ring by a second neck. The first neck has a smaller diameter than the second neck so as to facilitate movement of the combination of the alignment ring and the seal relative to the shaft, while maintaining desired relative alignment of the alignment ring with respect to the seal. Thus, the combination of the alignment ring and the seal tends to move as a unit with respect to the shaft (which may bend independently of the alignment ring and the seal).

22 The syringe body further includes a first mating assembly having diametrically opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to the neck and rigidly attached, respectively, to the first and second shoulders. Each rib has a plurality of generally planar locking faces generally parallel to and at a common predetermined distance from the neighboring shoulder surface.

23 The syringe further includes a generally conical mixing tip having an inlet end and a discharge end and a bore therethrough. The bore has a generally cylindrical portion at the inlet end and extends in a conically tapered portion toward the discharge end. The cylindrical bore portion is determined by a circumferential surface adapted to closely receive the body neck. A four section static mixing element is closely received and wedged within the bore tapered portion. The mixing tip has at the inlet end a second mating assembly having opposed generally planar, arcuate first and second locking tabs of a common predetermined thickness slightly less than the distance between the rib locking faces of the first mating assembly and the neighboring shoulder. Each tab has at least one edge beveled at a common predetermined angle. The tabs are symmetrically disposed with respect to the cylindrical bore portion. The bore circumferential surface includes diametrically opposed first and second detent recesses and first and second ramps which are contiguous at a proximal end, respectively, to the recesses.

24 Alternatively, a five section static mixing element is received and wedged within the bore tapered portion. It is believed that the use of a five section static mixing element will provide approximately 50% better mixing than the four section static mixing element. Those skilled in the art will appreciate that additional sections of the static mixing element will provide further

enhanced mixing and may therefore be desirable.

25 According to the preferred embodiment of the present invention, each section of the static mixing element comprises a single turn screw. Each screw is clocked, i.e., configured so as to be right or left handed, opposite that of each adjacent screw and is oriented, with respect to the leading and trailing edges thereof, at 90% with respect to each adjacent screw. Thus, as the two viscous materials flow from one screw to the next screw, the viscous materials are split into two portions, so as to effect desired mixing thereof. The screws are disposed upon a common shaft. The screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

26 The first and second mating assemblies are conjoined when the neck is inserted into the cylindrical bore portion in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration. The assemblies interlock when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess. Concurrently, each tab is closely received between one of the pluralities of rib locking faces and a shoulder. The mating assemblies are detachable when the mixing tip is rotated in the opposite direction until the neck and cylindrical bore portion are in the engaged configuration.

27 Optionally, a locking closure cap is utilized in place of the mixing tip so as to better mitigate leakage during shipping. The locking closure cap attaches to the body in the same manner as the mixing tip. Preferably, the locking closure cap comprises a locking closure cap liner formed of a comparatively resilient material which provides an enhanced seal between the locking closure cap and the body. The locking closure cap liner preferably comprises a groove formed therein and configured so as to receive a partition formed within the neck of the body.

DRAWING DESCRIPTION:

A more complete understanding of the present invention and other objects, aspects and advantages thereof will be gained from a consideration of the following description of the preferred embodiment read in conjunction with the accompanying drawings provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a double-barreled syringe according to the invention, including a double-plunger assembly, two pistons, a double-barrel assembly, a static mixing element, a detachable locking mixing tip, and alternatively, a detachable locking cap;

FIG. 2 is a discharge end perspective view of the FIG. 1 double-barrel assembly, including two shoulders, a neck with two outlet passages, and a mating assembly with two diametrically opposed detents and two symmetrically disposed locking ribs for engaging and interlocking with the mixing tip or cap;

FIG. 3 is an inlet end perspective view of the FIG. 1 mixing tip, including a mating assembly, having two locking tabs, which engages and interlocks with the FIG. 2 mating assembly;

FIG. 4A is a combined exploded perspective and partial sectional view of the FIGS. 2 and 3 mating assemblies before engagement;

FIG. 4B is a combined perspective and partial sectional view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 4C is a combined perspective and partial sectional view of the FIGS. 2 and 3

mating assemblies after interlocking;

FIG. 5A is a perspective view of the FIGS. 2 and 3 mating assemblies before engagement;

FIG. 5B is a perspective view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 5C is a perspective view of the FIGS. 2 and 3 mating assemblies after interlocking;

FIG. 6A is a transverse sectional view of the FIGS. 2 and 3 mating assemblies after engagement;

FIG. 6B is a transverse sectional view of the FIGS. 2 and 3 mating assemblies after interlocking;

FIG. 6C is a cross-sectional view of the FIG. 6B mating assemblies taken along offset line 6C--6C, showing each locking tab disposed within a recess determined by a FIG. 2 shoulder and locking rib;

FIG. 7 is a horizontal cross-sectional view of the FIG. 2 discharge end and FIG. 3 inlet end when the mixing tip is locked to the double-barrel assembly;

FIG. 8 is a cross-sectional view orthogonal to FIG. 7;

FIG. 9 is a perspective view of a unitary double-barreled plunger having integrally formed seals at the distal ends thereof;

FIG. 10 is an enlarged side view of one of the distal ends of the double-barreled plunger of FIG. 9, showing the seal;

FIG. 11 is a cross sectional perspective view of the distal end of the plunger of FIG. 10;

FIG. 12 is a horizontal cross-sectional view of an alternative configuration of the mixing tip, wherein a five element mixer is used instead of the four element mixer of FIGS. 7 and 8;

FIG. 13 is a cross-sectional view orthogonal to FIG. 12;

FIG. 14 is an enlarged side view of the five section mixing element of FIGS. 12 and 13;

FIG. 15 is a perspective view of a locking closure cap showing the locking closure cap liner thereof exploded therefrom;

FIG. 16 is an enlarged perspective view of the locking closure cap of FIG. 15, showing the locking closure cap liner installed therein; and

FIG. 17 is a discharge end perspective view of the double-barrel assembly, including two shoulders, a neck with two outlet passages separated by a straight partition, and a mating assembly with two diametrically opposed detents and two symmetrically disposed locking ribs for engaging and interlocking with the mixing tip or cap.

DETAILED DESCRIPTION:

1 DESCRIPTION OF THE PREFERRED EMBODIMENT

2 While the present invention is open to various modifications and alternative constructions, the preferred embodiment shown in the drawings will be described herein in detail. It is to be understood, however, there is no intention to limit the invention to the particular form disclosed. On the contrary, it is intended that the invention cover all modifications, equivalences and

alternative constructions falling within the spirit and scope of the invention as expressed in the appended claims.

3 The invention relates to an article of manufacture which is primarily intended for storing and dispensing gels which are components of an admixture and which need to be kept separate until the admixture is formed. However, the invention is not limited to particular types of material to be stored and dispensed, and can be used for storing and dispensing any material that can be placed within a syringe barrel and effectively admixed by a static mixing tip.

4 Where used herein, the word "attached" means that the two parts referred to (e.g., a locking rib and a shoulder or a plunger end-piece and a piston) are either molded in a single piece, or are glued or force-fitted together. However, other forms of attachment may be suitable, consistent with simplicity of manufacture and reliability of operation. Where used herein, the word "connected" means that the two parts referred to (viz., the two mating assemblies) can be easily separated after being joined together in an interlocking combination.

5 Referring to FIGS. 1 and 2, a syringe body 10 includes a double-barrel assembly 12 having juxtaposed first and second generally cylindrical barrels 14L, 14R having a common length and a generally cylindrical bore 16L, 16R, respectively, of a common diameter determining storage compartments 15L (not shown), 15R (not shown). Barrels 14L, 14R are bounded at a first (discharge) end 18L, 18R, respectively, by first and second shoulders 20L, 20R, respectively. The shoulders have generally planar surfaces 21L, 21R, respectively, which are coplanar and contiguous. A generally cylindrical neck 22 extends from and is symmetrically disposed between the shoulders. As shown in FIG. 2, neck 22 includes first and second outlet passages 24L, 24R, divided by a partition 26. As best shown in FIG. 7, passages 24L, 24R are in fluid communication, respectively, with barrels 14L, 14R. Barrels 14L, 14R are open at an opposite (plunger) end 28L, 28R, respectively, which closely receives a piston 30L, 30R, respectively. Barrel ends 28L, 28R are circumscribed by and rigidly attached to an arcuately-shaped finger-grip 32.

6 The syringe body 10 further includes a double-plunger assembly 36 having juxtaposed generally cylindrical first and second plungers 38L, 38R of a common length. Each plunger extends at an end 40L, 40R proximal to a piston in an end-piece 42L, 42R rigidly attached to the piston 30L, 30R, respectively. The plungers are attached at their distal end 44L, 44R to a disc-shaped thumb-rest 46 so that when the thumb-rest is depressed the plungers move forward in tandem, and the attached pistons move in tandem within the barrels.

7 Still referring to FIG. 2, syringe body 10 further includes a first mating assembly 50 having diametrically opposed first and second detents 52, 54 extending outwardly from neck 22, and opposed first and second locking ribs 56L, 56R symmetrically disposed with respect to neck 22. Ribs 56L, 56R each have a first (stand-off) portion 57L, 57R, respectively, generally parallel to the shoulders 20L, 20R, respectively, and generally orthogonal to a second (bracket) portion 58L, 58R (not shown), respectively, rigidly attached, respectively, to shoulders 20L, 20R. Rib stand-off portions 57L, 57R each have two generally planar locking faces 59L, 60L, and 59R (not shown), 60R (not shown), respectively, which are generally parallel to and at a common distance from the neighboring shoulder surface 21L, 21R, respectively, thus determining symmetrical recesses 62L, 62R (not shown), respectively. Preferably, double-barrel assembly 12, including neck 22, and mating assembly 50 are fabricated as a unit from a polymerized alkene such as polypropylene by means of an injection molding process.

8 Referring to FIGS. 1 and 3, a generally conical mixing tip 70 includes an inlet end 72 and a discharge end 74 and a bore 76 therethrough. As best shown in FIG. 3, bore 76 has a generally cylindrical portion 78 proximate to inlet end 72 and extends in a conically tapered portion 80 (not shown) toward the discharge end 74. Cylindrical bore portion 78 is determined by a circumferential surface 78S

adapted to closely receive the neck 22. As best shown in FIGS. 7 and 8, a static mixing element 82 is closely received and wedged within the tapered bore portion 80. The static mixing element 82 comprises a four section static mixing element. That is, the mixing element 82 is comprised of four separate single turn screws. Mixing element 82 is inserted in a random azimuthal orientation within bore portion 80 and so is not disposed in a predetermined orientation with respect to partition 26 and outlet passages 24L, 24R when mixing tip 70 is attached to double-barrel assembly 12. As further shown in FIGS. 7 and 8, when tip 70 and assembly 12 are attached, proximate end 82P of mixing element 82 and neck 22 are separated by a gap 83. Mixing tip 70 further includes an indented surface portion 84 to facilitate a person holding the tip between the thumb and fingers to rotate the tip.

9 Still referring to FIG. 3, the inlet end 72 of mixing tip 70 includes a second mating assembly 90 having opposed generally planar arcuately-shaped first and second locking tabs 92, 94 of a common predetermined thickness slightly less than the common width of recesses 62L, 62R. Tabs 92, 94 are symmetrically disposed with respect to cylindrical bore portion 78 and have edges 93A (not shown), 93B (not shown) and 95A, 95B, respectively, which are each beveled at an angle of about 8 degrees. Tabs 92, 94 are rigidly attached, respectively, to structural ribs 98, 100 disposed symmetrically with respect to bore portion 78, and extending in generally oval-shaped collar portions 102, 104, respectively. The two collar portions partially circumscribe inlet end 72 and extend so that tab 92 is rigidly attached at an interior edge 92E (not shown) to collar portion 104, and tab 94 is rigidly attached at an interior edge 94E to collar portion 102. Surface 78S includes diametrically opposed first and second detent recesses 110, 112 and a plurality of corrugations 114. As shown in FIGS. 4A, 4B, 6A and 6B, recesses 110, 112 are each contiguous to first and second ramps 116, 118, respectively, which are generally planar sloping portions of the surface 78S. As shown in FIGS. 4B and 6A, when neck 22 is inserted within bore portion 78, each detent 52, 54 contacts a ramp 116, 118, respectively, at a ramp end 120, 122, respectively, distal to recess 110, 112, respectively. As shown in FIGS. 4C and 6B, when mixing tip 70 is rotated counterclockwise with respect to double-barrel assembly 12, each detent 52, 54 traverses the contacting ramp to the proximal ramp end 124, 126, and is received within the recess. Preferably, mixing tip 70

10 and associated mating assembly 90 are fabricated as a unit from a polymerized alkene such as polypropylene by means of an injection molding process. As shown in FIG. 1, mixing tip 70 may be replaced by a closure cap 130 having a mating assembly identical to mating assembly 90 so that cap 130 is interchangeable with mixing tip 70.

11 FIGS. 4A and 5A show the proper relative orientation between mating assemblies 50 and 90 so that neck 22 can be inserted into bore portion 78. FIGS. 4B and 6A show the mating assemblies engaged but not yet interlocked. FIG. 5B shows the disposition in the engaged position of collar portion 102 with respect to locking ribs 56L, 56R of mating assembly 50. In FIGS. 4B and 6A, arrows 120, 121 show the (counterclockwise) rotational direction for interlocking. FIGS. 4A and 4B show rib stand-off portions 57L and 57R with respective locking faces 59L, 60L and 59R, 60R. FIGS. 4B and 6A further show the respective disposition of locking tabs 92, 94 of mating assembly 90 and rib stand-off portions 57L, 57R of mating assembly 50 before interlocking. FIGS. 4C and 6B show the respective disposition of locking tabs 92, 94 and rib stand-off portions 57L, 57R after interlocking when tabs 92, 94 have been closely received within recesses 62L, 62R, respectively, and detents 52, 54 received within recesses 110, 112, respectively. Tab insertion and removal are facilitate by beveled edges 93A, 93B of tab 92 and beveled edges 95A, 95B of tab 94. FIG. 5C shows the disposition in the interlocked position of collar portion 102 with respect to locking ribs 56L, 56R. FIGS. 6 and 7 show locking tabs 92, 94 received within recesses 62L 62R, respectively, determined, respectively, by shoulders 20L, 20R and rib stand-off portions 57L, 57R with locking faces 59L, 60L and 59R, 60R. As best shown in FIG. 7, locking tabs 92, 94, when received within recesses 62L, 62R, contact locking faces 59L, 60L and 59R, 60R, respectively. FIG. 8 shows detents 52, 54 in relation, respectively, to recesses 110, 112 and

to collar portions 102, 104.

12 After dispensing a desired amount of admixture, a user typically would detach the mixing tip 70 from the double-barrel assembly 12 by rotating the tip clockwise until detents 52, 54 reach ramp distal ends 120, 122, at which position locking tabs 92, 94 are disengaged from recesses 62L, 62R, and then pulling apart the mixing tip and double-barrel assembly. The corrugation in surface 78S contiguous to each ramp distal end acts as a stop for the detent, thus preventing over-rotation and ensuring that mating assemblies 50 and 90 return to the engaged position. The closure cap 130 may then be connected to the syringe body 10 by using the same engagement and locking procedure as used for the tip.

13 Preferably, the double-barrel assembly 12 and attached mating assembly 50, double-plunger assembly 36, mixing tip 70 and attached mating assembly 90, and closure cap 130 are fabricated from a polymerized alkene such as polypropylene. Preferably, the length between thumb-rest 46 and discharge end 74 of mixing tip 70 is about 6.75 inches when plungers 38L, 38R are fully retracted. Preferably, the combined width of juxtaposed barrels 14L, 14R is about 0.65 inch.

14 Referring now to FIGS. 9-11, the plunger alternatively comprises a unitary construction double-barreled plunger 336 having sealing tips 200L and 200R formed integrally with shafts 210L and 210R of the plungers 338L and 338R thereof. In this manner, the need for separate sealing tips, such as those of pistons 30L and 30R of FIG. 1, is eliminated. By eliminating such separate sealing tips, both the materials and assembly costs associated with the plunger assembly 336 are reduced.

15 With particular reference to FIGS. 10 and 11, the right sealing tip 200R comprises a shaft 210R having a first neck 212 attaching the shaft to 210R to an alignment ring 204 and a second neck 208 attaching the alignment ring 204 to a seal 202R. Although only the distal end of one plunger 338R is shown in FIGS. 10 and 11, it will be appreciated that both plungers 338L and 338R are substantially identical.

16 The shaft 210R has a diameter, Dimension A, which is substantially greater than a diameter, Dimension B, of the first neck 212. The diameter of the shaft 210R, Dimension A, is somewhat less than the diameter of the cylindrical bore 16R (FIG. 1) within which the shaft 210R is disposed, so as to facilitate easy movement of the shaft 210R within the cylindrical bore 16R. The alignment ring 204 comprises a first portion 214 having a diameter, Dimension C, which is approximately equal to the diameter, Dimension A, of the shaft 210R. The alignment ring 204 also has a second portion 216 which has a diameter, Dimension D, which is greater than the diameter, Dimension C, of the first portion 204 thereof. The diameter, Dimension D, of the second portion 216 of the alignment ring 204 is approximately equal to the diameter of the cylindrical bore 16R within which the plunger 338R is slidably disposed, so as to provide a close fit therewith. The second portion 216 preferably defines a radiused or rounded surface where it contacts the cylindrical bore 16R.

17 Second neck 208 has a diameter, Dimension E, which is less than the diameter, Dimension C, of the first portion 214 of the alignment ring 204 and which is greater than the diameter, Dimension B, of the first neck 212.

18 The seal 202R has a first portion 220 which has a diameter, Dimension F, which is approximately equal to the diameter, Dimension D, of the second portion 216 of the alignment ring 204 (and which is thus approximately equal to the diameter of the cylindrical bore 16R). The seal 202R also has a second portion 206 which has a diameter, Dimension G, which is substantially greater than the diameter, Dimension F, of the first section 220 of the seal 202R. The second section 206 of the seal 202R is defined by a flare which is comprised of a relatively thin, and consequently comparatively flexible, portion of the seal 202R, and which therefore conforms generally in diameter to the cylindrical bore 16R. In this manner, the second portion 206 of the seal 202R provides a

seal between the plunger 38Y and the first bore 16R within which the plunger 338R is disposed.

19 The alignment ring 204 functions so as to maintain desired alignment of the seal 202R with respect to the cylindrical bore 16R, particularly during use, e.g., dispensing of fluid, of the syringe. During use of the double-barreled syringe, the shaft 210R tends to flex or bow as the thumb rest 46 is pushed so as to force viscous material from the cylindrical bore 16R. The alignment ring 204 mitigates misalignment of the seal 202R and consequent undesirable leakage of viscous material thereby. The alignment ring 204, in combination with the neck 208 and the seal 202R, define a spool-like member which is substantially more resistant to misalignment within the cylindrical bore 16L than is the seal 202R alone.

20 The first neck 212, which has a substantially smaller diameter, Dimension B, than the diameter, Dimension E, of the second neck 208, permits some desired movement of the shaft 210R of the plunger 338R, with respect to the combination of the alignment ring 204 and the seal 202R (which are rigidly attached to one another) such that bending of the shaft 210R does not effect substantial misalignment of the seal 202R.

21 The diameter, Dimension C, of the first section 214 of the alignment ring 204 is substantially less than the diameter of the cylindrical bore 16R, and the second section 216 of the alignment ring 204 has a diameter, Dimension D, approximately equal to that of the diameter of the cylindrical bore 16R, so as to provide a desired amount of friction between the alignment ring 204 and the cylindrical bore 16R. The radiused or rounded contact surface of the second section 216 also contributes to providing the desired amount of friction between the alignment ring 204 and the cylindrical bore 16R. According to the preferred embodiment of the present invention, Dimension A is approximately 0.241 inch, Dimension B is approximately 0.129 inch, Dimension C is approximately 0.238 inch, Dimension D is approximately 0.250 inch, Dimension E is approximately 0.165, Dimension F is approximately 0.250 inch and Dimension G. is approximately 0.260 inch. The unitary construction double-barreled plunger 336 is preferably fabricated from a polymerized alkene such as polypropylene.

22 Referring now to FIGS. 12-14, the mixing tip 70A alternatively comprises a five section static mixing element 82A. The five section static mixing element 82A comprises first 240A, second 240B, third 240C, fourth 240D and fifth 240E sections. Each section 240A-240E of the static mixing element 82A preferably comprises a single turn screw formed upon a common shaft 242 (best shown in FIG. 14) such that each section has a different clock sense, i.e., rotates in a different direction, from each adjacent section. That is, if the screw of a given section 240A-240E is clockwise, then any immediately adjacent section(s) will have a counter clockwise sense. Further, the leading edge of each screw is oriented at approximately 90 degrees with respect to the trailing edge of each preceding screw, such that as fluid flows from one screw to another, the fluid is cut approximately in half, so as to effect desired mixing thereof. The five section static mixing element 82A is preferably fabricated from a polymerized alkene such as polypropylene.

23 Referring now to FIGS. 15 and 16, a locking closure cap 130 preferably comprises a locking closure cap liner 260 for enhancing the seal between the locking closure cap 130 and the neck 22 so as to prevent undesirable leakage of fluids from the first 14L and second 14R cylindrical barrels.

24 According to the preferred embodiment of the present invention, the locking closure cap liner 260 comprises a base 262 and two outwardly extending protrusions 264 and 266 which define a groove 268 therebetween. The groove 268 is configured so as to receive a generally planar partition 26A of the neck 22, as shown in FIG. 17. The two protrusions fit tightly within the two outlet passages 24L and 24R so as to effect desired sealing thereof. The base 262 provides further sealing as it is compressed against the neck 22 by the locking

closure cap 130. The base 262 of the locking closure cap 130 is preferably compressed by approximately 0.008 inch when the locking closure cap 130 is attached to the syringe body 10.

25 The locking closure liner is preferably fabricated from polyolefin elastomer, preferably ENGAGE 8401 (ENGAGE is a federally registered trademark of Dupont Dow Elastomers). The locking closure cap is preferably fabricated form a polymerized alkene, such as polypropylene.

26 The locking closure cap liner 260 is preferably installed within the locking closure cap by inserting the two outwardly extending protrusions 264 and 266 into the neck 22 such that the partition 26A is received within the locking closure cap liner 260. Then, the locking closure cap 130 is attached to the syringe body 10 in the same manner that the mixing tip 70 is attached thereto. The partition 26A prevents rotation of the locking closure cap liner 260 as the locking closure cap 130 is rotated into the individual position thereof.

27 All of the polypropylene components of the present invention are preferably comprised of Polymerland 3320 AP polypropylene.

28 It is understood that the exemplary double-barreled syringe described herein and shown in the drawings represents only a presently preferred embodiment of the invention. Indeed, various modifications and additions may be made to such embodiment without departing from the spirit and scope of the invention. For example, the unitary construction plunger may alternatively comprise a plurality of alignment rings. Further, various different configurations of the locking closure cap liner are contemplated. Further, various numbers and configurations of the individual sections of the static mixing element are contemplated.

29 Thus, these and other modifications and additions may be obvious to those skilled in the art and may be implemented to adapt the present invention for use in a variety of different applications.

CLAIMS:

What is claimed is:

1. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, the surfaces coplanar and contiguous, a generally, cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having a plurality of generally planar locking faces generally parallel to and at a common distance from said shoulder surface;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the mixing tip is rotated in a first direction until each detent, traversing the ramp and

reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a five section static mixing element disposed within the mixing tip to mix the two viscous materials as the two viscous materials are dispensed from the first and second barrels.

2. The syringe of claim 1, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

3. The syringe of claim 2, wherein the screws are disposed upon a common shaft.

4. The syringe of claim 2, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

5. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof.

6. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having an alignment ring formed proximate a distal end thereof and a seal formed distal of the alignment ring, each alignment ring enhancing alignment of a seal with respect to the one of the barrels.

7. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring coupled comparatively flexibly to the shaft of the plunger and the alignment ring coupled comparatively rigidly to the seal.

8. The syringe of claim 1, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring attached

to the shaft by a first neck and the seal attached to the alignment ring by a second neck, the first neck having a smaller diameter than the second neck to facilitate movement of the alignment ring and the seal relative to the shaft.

9. The syringe of claim 1, further comprising a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

10. The syringe of claim 9, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the partition.

11. A syringe for dispensing two viscous materials as an admixture, comprising a body and a mixing tip:

the body comprising a double-barrel assembly having juxtaposed first and second barrels having a common length and a generally cylindrical bore of a common diameter, each barrel bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, the surfaces coplanar and contiguous, a generally cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels, each barrel at an opposite end circumscribed by a common finger-grip closely receiving within said bore a piston;

the body further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof, the seal comprising a flare having a wall thickness which is sufficiently thin as to flexibly conform to one generally cylindrical bore and seal one plunger with respect thereto;

the body further comprising a first mating assembly having diametrically opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having a plurality of generally planar locking faces generally parallel to and at a common predetermined distance from said shoulder surface;

the mixing tip having an inlet end and a discharge end and a bore therethrough, the bore having a generally cylindrical portion at the inlet end and extending in a conically tapered portion toward the discharge end, said cylindrical portion determined by a circumferential surface adapted to closely receive said neck, a static mixing element being closely received and wedged within the tapered portion;

the mixing tip having at the inlet end a second mating assembly having opposed generally planar, arcuate first and second locking tabs of a common predetermined thickness less than said first mating assembly predetermined distance, each tab having at least one edge beveled at a common predetermined angle, the tabs symmetrically disposed with respect to said cylindrical bore portion, said circumferential surface having diametrically opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the first and second mating assemblies conjoining when the neck is inserted into the cylindrical bore portion in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction until the neck and cylindrical bore portion are in said engaged configuration.

12. The syringe of claim 11, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto, such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

13. The syringe of claim 12, wherein the screws are disposed upon a common shaft.

14. The syringe of claim 12, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

15. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, the surfaces coplanar and contiguous, a generally, cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having a plurality of generally planar locking faces generally parallel to and at a common distance from said shoulder surface;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction until the neck and bore are in said engaged configuration; and

a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

16. The syringe of claim 15, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the partition.

17. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, a generally cylindrical neck extending from and symmetrically disposed between

the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck is inserted into the bore, and said mating assemblies interlocking when the mixing tip is rotated in a first direction until each tab is closely received between a locking rib and one of said first and second shoulders, the mating assemblies detachable when the mixing tip is rotated in the opposite direction, and a static mixing element disposed within the mixing tip to mix the two viscous materials as the two viscous materials are dispensed from the first and second barrels; and

a unitary construction double plunger having juxtaposed first and second plungers of a common length, said plungers slidably mounted in said barrels for dispensing the viscous materials therefrom as the plungers are pushed into said barrels.

18. The syringe of claim 17, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

19. The syringe of claim 18, wherein the screws are disposed upon a common shaft.

20. The syringe of claim 18, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

21. The syringe of claim 17, wherein the generally of planar surfaces of each shoulder are coplanar and contiguous, the first mating assembly has opposed first and second detents extending outwardly from the neck, wherein the mixing tip circumferential surface has opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses within the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration and wherein said mating assemblies interlocking when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess.

22. The syringe of claim 17, wherein each of said unitary construction double-plungers has a seal formed integrally therewith at a distal end thereof.

23. The syringe of claim 17, wherein each of said unitary construction double-plungers have an alignment ring formed proximate a distal end thereof and a seal formed distal of the alignment ring, each alignment ring enhancing alignment of a seal with respect to the one of the barrels.

24. The syringe of claim 17, wherein each of said unitary construction double-plungers has a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring coupled comparatively flexibly to the shaft of the plunger and the alignment ring coupled comparatively rigidly to the seal.

25. The syringe of claim 17, wherein each of said unitary construction double-plungers has a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring attached to the shaft by a first neck and the seal attached to the alignment ring by a second neck, the first neck having a smaller diameter than the second neck to facilitate movement of the alignment ring and the seal relative to the shaft.

26. The syringe of claim 17, wherein each of said first and second locking ribs include at least one generally planar locking face generally parallel to said shoulder surface.

27. The syringe of claim 26, wherein the first mating assembly has opposed first and second detents extending outwardly from the neck, said syringe further comprising a locking closure cap having a generally cylindrical bore determined by a circumferential surface sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between said at least one rib locking face and one of said first and second shoulders, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

28. The syringe of claim 27, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the

partition.

29. The syringe of claim 17, wherein the static mixing element comprises five single turn screws.

30. The syringe of claim 17, wherein each rib has a plurality of generally planar locking faces.

31. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, the surfaces coplanar and contiguous, a generally, cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second detents extending outwardly from the neck, and opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a

proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the mixing tip is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is received between the rib and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction, and a static mixing element disposed within the mixing tip to mix the two viscous materials as the two viscous materials are dispensed from the first and second barrels.

32. The syringe of claim 31, wherein each locking rib has a plurality of generally planar locking faces generally parallel to and at a common distance from said shoulder surface and each tab is received between one of the pluralities of rib locking faces and a shoulder.

33. The syringe of claim 31, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

34. The syringe of claim 33, wherein the screws are disposed upon a common shaft.

35. The syringe of claim 33, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

36. The syringe of claim 31, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof.

37. The syringe of claim 31, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having an alignment ring formed proximate a distal end thereof and a seal formed distal of the alignment ring, each alignment ring enhancing alignment of a seal with respect to the one of the barrels.

38. The syringe of claim 31, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring coupled comparatively flexibly to the shaft of the plunger and the alignment ring coupled comparatively rigidly to the seal.

39. The syringe of claim 31, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring attached to the shaft by a first neck and the seal attached to the alignment ring by a second neck, the first neck having a smaller diameter than the second neck to facilitate movement of the alignment ring and the seal relative to the shaft.

40. The syringe of claim 31, further comprising a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp

proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

41. The syringe of claim 40, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the partition.

42. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, a generally cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having at least one locking face;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck is inserted into the bore, and said mating assemblies interlocking when the mixing tip is rotated in a first direction until each tab is received between a rib locking face and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction, and a static mixing element disposed within the mixing tip to mix the two viscous materials as the two viscous materials are dispensed from the first and second barrels, wherein said static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw, and wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

43. The syringe of claim 42, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof.

44. The syringe of claim 42, further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having an alignment ring formed proximate a distal end thereof and a seal formed distal of the alignment ring, each alignment ring enhancing alignment of a seal with respect to the one of the barrels.

45. The syringe of claim 42, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring coupled comparatively flexibly to the shaft of the plunger and the alignment ring coupled comparatively rigidly to the seal.

46. The syringe of claim 42, further comprising a unitary construction double-plunger having juxtaposed first and second plungers, each plunger having a shaft, an alignment ring formed at a distal end of the shaft and a seal formed distally of the alignment ring, the alignment ring attached to the shaft by a first neck and the seal attached to the alignment ring by a second neck, the first neck having a smaller diameter than the second neck to facilitate

movement of the alignment ring and the seal relative to the shaft.

47. The syringe of claim 42, further comprising a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, said surface having opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, the mating assemblies conjoining when the neck is inserted into the bore in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, the mating assemblies interlocking when the locking closure cap is rotated in a first direction until each detent, traversing the ramp and reaching the ramp proximal end, is received within a recess, and each tab is closely received between one of said pluralities of rib locking faces and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction until the neck and bore are in said engaged configuration, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to Litigate leakage of the two viscous materials from the first and second barrels.

48. The syringe of claim 47, wherein the neck comprises a partition and the locking closure cap liner comprises a groove configured to receive the partition.

49. A syringe for dispensing two viscous materials as an admixture, comprising a body and a mixing tip:

the body comprising a double-barrel assembly having juxtaposed first and second barrels having a common length and a generally cylindrical bore of a common diameter, each barrel bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, a generally cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels, each barrel at an opposite end circumscribed by a common finger-grip;

the body further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof, the seal comprising a flare having a wall thickness which is sufficiently thin as to flexibly conform to one generally cylindrical bore and seal one plunger with respect thereto;

the body further comprising a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders;

the mixing tip having an inlet end and a discharge end and a bore therethrough, the bore having a generally cylindrical portion at the inlet end and extending in a conically tapered portion toward the discharge end, said cylindrical portion determined by a circumferential surface adapted to closely receive said neck, a static mixing element being closely received and wedged within the tapered portion;

the mixing tip having at the inlet end a second mating assembly having opposed first and second locking tabs of a common predetermined thickness less than said first mating assembly predetermined distance, the tabs symmetrically disposed with respect to said cylindrical bore portion, the first and second mating assemblies conjoining when the neck is inserted into the cylindrical bore portion and said mating assemblies interlocking when the mixing tip is rotated in a first direction until each tab is closely received between a locking rib and one of said first and second shoulders, the mating assemblies detachable when the mixing tip is rotated in the opposite direction until the neck and cylindrical bore portion are in said engaged configuration.

50. The syringe of claim 49, wherein the mixing tip has a static mixing element disposed therein.

51. The syringe of claim 50, wherein the static mixing element comprises five single turn screws.

52. The syringe of claim 49, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto, such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

53. The syringe of claim 52, wherein the screws are disposed upon a common shaft.

54. The syringe of claim 49, wherein each of said first and second locking ribs include at least one generally planar locking face generally parallel to said shoulder surface.

55. The syringe of claim 52, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

56. A syringe for dispensing two viscous materials as an admixture, comprising a body and a mixing tip:

the body comprising a double-barrel assembly having juxtaposed first and

second barrels having a common length and a generally cylindrical bore of a common diameter, each barrel bounded at a discharge end by first and second shoulders, respectively, a neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

the body further comprising a unitary construction double-plunger having juxtaposed first and second plungers of a common length, each plunger having a seal formed integrally therewith at a distal end thereof, the seal comprising a flare having a wall thickness which is sufficiently thin as to flexibly conform to one generally cylindrical bore and seal one plunger with respect thereto;

the body further comprising a first mating assembly opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having at least one of generally planar locking face at a common predetermined distance from said shoulder surface;

the mixing tip having an inlet end and a discharge end and a bore therethrough, the bore having a generally cylindrical portion at the inlet end and extending in a conically tapered portion toward the discharge end, said cylindrical portion determined by a circumferential surface adapted to closely receive said neck, a static mixing element being closely received and wedged within the tapered portion, said mixing tip having at the inlet end a second mating assembly having opposed said first and second locking tabs of a common predetermined thickness less than said first mating assembly predetermined distance, the first and second mating assemblies conjoining when the neck is inserted into the cylindrical bore portion, the mating assemblies interlocking when the mixing tip is rotated in a first direction until each tab is closely received between a rib locking face and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction.

57. The syringe of claim 56, wherein each shoulder has a generally planar surface, wherein said surfaces are coplanar and contiguous.

58. The syringe of claim 56, wherein the first mating assembly has diametrically opposed first and second detents extending outwardly from the neck, wherein said circumferential surface has diametrically opposed first and second detent recesses and first and second ramps contiguous at a proximal end, respectively, to said recesses, and wherein said first and second mating assemblies conjoin when the neck is inserted into the cylindrical bore portion in a relative orientation such that each detent contacts a ramp distal end, thereby determining an engaged configuration, and said mating assemblies interlock when the mixing tip is rotated in a first direction until each detent traverses the ramp and reaches the ramp proximal end and is received within a recess.

59. The syringe of claim 56, wherein the static mixing element comprises a plurality of single turn screws, each screw rotating in a direction opposite that of an adjacent screw and oriented at 90 degrees with respect thereto, such that as the two viscous materials flow from one screw to the next screw the viscous materials are split into two portions to effect mixing thereof.

60. The syringe of claim 59, wherein the screws are disposed upon a common shaft.

61. The syringe of claim 59, wherein the screws taper in size such that the viscous materials flow through successively smaller screws as the viscous materials are dispensed.

62. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, a generally, cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck is inserted into the bore and interlocking when the mixing tip is rotated in a first direction until each tab is received between a rib and a shoulder, the mating assemblies detachable when the mixing tip is rotated in the opposite direction; and

a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck is inserted into the bore and interlocking when the locking closure cap is rotated in a first direction until each tab is received between a rib and a shoulder, the mating assemblies detachable when the locking closure cap is rotated in the opposite direction, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscous materials from the first and second barrels.

63. The syringe of claim 62, wherein each of said first and second locking ribs including at least one generally planar locking face generally parallel to said shoulder surface.

64. The syringe of claim 62, wherein the neck comprises a partition and the

locking closure cap liner comprises a groove configured to receive the partition.

65. A syringe for dispensing two viscous materials as an admixture, comprising:

first and second barrels each bounded at a discharge end by first and second shoulders, respectively, each shoulder having a generally planar surface, a generally cylindrical neck extending from and symmetrically disposed between the shoulders, the neck including first and second outlet passages in fluid communication, respectively, with the first and second barrels;

a first mating assembly having opposed first and second locking ribs symmetrically disposed with respect to said neck and rigidly attached, respectively, to said first and second shoulders, each rib having at least one locking face;

a mixing tip having an inlet end having a generally cylindrical bore determined by a circumferential surface adapted to closely receive said neck, a second mating assembly having opposed first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck is inserted into the bore, and said mating assemblies interlocking when the mixing tip is rotated in a first direction until each tab is closely received between said at least one rib locking face and one of said first and second shoulders, the mating assemblies detachable when the mixing tip is rotated in the opposite direction, and a static mixing element disposed within the mixing tip to mix the two viscous materials as the two viscous materials are dispensed from the first and second barrels; and a locking closure cap having a generally cylindrical bore sized to receive said neck, a second mating assembly having opposed generally planar first and second locking tabs symmetrically disposed with respect to said bore, the mating assemblies conjoining when the neck inserted into the bore when said mating assemblies interlocking when the locking closure cap is rotated in a first direction so that each tab is closely received between said at least one rib locking face and one of said first and second shoulders, and a locking closure cap liner comprised of a resilient polymer material disposed within the locking closure cap and configured to engage and seal the neck to mitigate leakage of the two viscus materials from the first and second barrels.